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On November 8 and 9, 2001, leading experts in patient safety, medical informatics, advanced surgical devices, telesurgery, and surgical facilities met to formulate strategic directions for "OR of the Future" in both military and civilian healthcare. Co-hosted by the University of Maryland Medical Center and the Telemedicine and Advanced Technology Research Center (U.S. Army Medical Research and Materiel Command), researchers, surgeons, and experts in the field of operating room technology addressed the current state of research and technological developments. Experts in patient safety, medical informatics, advanced surgical devices, telesurgery, and surgical facilities met in focused work groups to develop a proposed research agenda for each content area. Each workgroup produced a white paper in their topic areas. The white papers have been completed and published by TATRC on the TATRC website. Publication in professional periodicals and journals is now under consideration.

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David W Rattner, MD
Adrian Park, MD

CURRENT STATE OF TECHNOLOGY

For most of the history of medicine, physicians relied on the direct evidence of their senses (primarily vision and touch) to diagnose illness, monitor the condition of patients, and perform invasive procedures. Minimally invasive therapy changes this traditional paradigm. Anatomical information is now presented as either radiographic or video images. These modalities display anatomic data in two dimensions making localization of target lesions and navigation to the desired area through small incisions more difficult. The surgeon/clinician's direct line of sight is disrupted, resulting in a "visual disconnection" from the operative field. There are a variety of imaging modalities, which can guide minimally invasive therapies. While CT and MRI provide detailed information, they are expensive, cumbersome and not generally suited to routine use in an operating room. In contrast, Ultrasound is widely available, relatively inexpensive and provides real time images. Unfortunately, US often provides images -which are difficult to interpret in terms of spatial orientation. By registering intra -operative US to preoperative 3D data sets obtained from CT and/or MRI, the limitations of US as a navigational tool may be overcome. This will allow the surgeon to have "x ray vision" to see through solid organs and get to the target are with minimal collateral damage to the surrounding organs.

Two further, major consequences of minimal access approaches are i) the loss of degrees of (operative) movement and ii) the loss of tactile feedback. While performing conventional open surgery, the surgeon has use of the joints of his or her hands, wrists and elbows. This allows the operator more than 20 degrees of movement and as a result, great flexibility to access and dissect target anatomy from various angles and approaches. The laparoscopist by comparison, working with instruments inserted into the abdomen through trochars fixed in the abdominal wall is limited (depending upon the instrument's "end effector") to between 4 and 6 degrees of movement while operating. This limitation may add considerably to the difficulty of performing advanced and basic minimally invasive surgical maneuvers. The surgeon often finds himself working around the constraints of his relatively fixed instruments rather then having the surgery facilitated or enhanced by these instruments. Tactile feedback is an important method of locating abnormal tissue, identifying blood vessels and fluid filled structures, and gauging the amount of force one is applying as tissue is manipulated. Force feedback can be important in the performance of delicate dissection as well as guiding deployment of sutures and devices. While robotic surgical systems have enhanced the ability of surgeons to perform fine motor activities at a microsurgical scale, the absence of force feedback has left open the possibility for unintended tissue damage due to application of excessive force in retraction, dissection, and tissue manipulation. The incorporation of tactile sensation to both standard laparoscopic instruments and computer assisted surgical systems will enhance the capabilities of these systems and potentially increase their safety.

Increasingly physicians find themselves relying on ever-more sophisticated artificial sensing devices. Some, like the cameras used in minimally invasive procedures, augment the traditional senses. Others, like pulse oximetry provide entirely different kinds of information to the physician. Unfortunately, the technology used to process patient data has not kept up with the ability to collect it. During a procedure, medical personnel monitor separate streams of data, most frequently one for each sensor. Clearly, this will not scale as the number of sensors and the number of kinds of sensors increases, Therefore a focus area will be data capture and use. This will include the capture of correlated data directly from multiple sensors in the operating environment as well as its storage in a format that facilitates queries and analysis. Attention will be devoted to both real-time analysis during procedures and offline ex post facto analysis. There will likely be a need to develop new algorithms for extracting relevant information from masses of data. Among other things, attention will be devoted to understanding causes of medical error and to inventing mechanisms that reduce the incidence of such errors.

The recent Institute of Medicine report "To Err is Human" focused pubic attention on the prevalence of preventable medical errors. Many adverse outcomes are the result of a combination of several related actions during a therapeutic intervention. The proliferation of computer systems and databases provides an environment rich in data relating to patients, providers, and processes of care. Unfortunately, these systems are used primarily to transmit laboratory data and billing information. One difficulty in analyzing this data is the large number of variables and the complex and poorly understood relationship among these variables. Simple statistical analysis will not serve to shed much light in this complex milieu. Outside the medical sector, people have begun to use a technique called machine learning to try to pull information out of complex sets of data. With some guidance, it can be used to infer relationships that are not readily apparent. By applying these techniques to data gathered from multiple operative procedures we intend to identify trends and patterns predictive of adverse events so that intervention can be applied before irreversible harm occurs.

When new technology is introduced, claims of improved efficiency are often made. Yet, as one looks at today's operating room, one sees a high density of complex machinery, often arrayed in an ergonomically unsafe fashion. While the designs are aesthetically pleasing, the benefit of new architectural designs and staffing models has not yet been quantified and measured. In order to fully capture the purported benefits of the components of the OR of the Future as well as the efficiencies of systems integration, it is necessary to model, predict, and then measure the effect of different patient flow schemes, different staffing models and room functionality in the presence or absence of its various components. Only by performing such a detailed analysis can one justify the potential added expenses of such a sophisticated OR environment and identify areas of waste which should be modified or eliminated from the design.

DESIRED STATE OF TECHNOLOGY

In the next five years major thrusts should include:

1) developing and designing an entirely new generation of "smart instruments". Advances in minimally invasive surgical instrumentation over the past several decades have been incremental. Simply put, more refined and variable end effectors have been affixed to the existing "chop sticks". Hand piece design has seen little innovation and virtually no incorporation of modern ergonomic principles. "Smart instruments" will restore tactile feedback to the minimally invasive surgeon. Instrument end effectors with "sense and discern" capabilities will be able to recognize different tissues and pathological states and correspondingly guide tissue manipulation, dissection and cutting with enhanced precision.

Smart instruments will also allow the surgeon full operative degrees of movement, independent of a fully robotic platform. The surgeon may or may not be directly connected via the hand piece/actuator to the end effector. Direction/activation of the end effector may occur via an ergonomically designed hand piece, or by a more sophisticated/complex glove or gesture recognition mechanism.

2) augmenting image guided techniques. This may best be accomplished by integrating ultrasound probes with robotic and manual instruments to provide intra-operative guidance. An essential component will be by registering ultrasound images to the video images provided by a laparoscope and registering ultrasound images to pre-operative CT and MR data sets. When current technology matures, 3D ultrasound will be incorporated real-time into the OR.

3) developing the ability to collect, analyze, intelligently display and store data from the patient, from the procedure and from the operating room environment. To accomplish this it will be necessary to design an architect for sensors on the patient that collects data independent of patient location or procedure. This may be best addressed through the use of both wireless and radio-frequency identification technologies.

4) developing algorithms to extract relevant information from this data for intra-operative guidance and post-operative analysis; and developing methods to present that data during the procedure to medical personnel in a meaningful way. This will likely require application of the methods of machine learning to the data captured from surgical procedures to infer relationships between the data and outcomes that because of the number and complexity of the data points are not readily apparent.

5) creating a "plug and play" environment. Current devices neither communicate with each other nor with common interfaces. All devices in the future should be able to be seamlessly plugged into a network for control, data capture, and safety. A DICOM like standard needs to be created for all equipment used in future ORs. Furthermore, this standard needs to provide interoperability in both civilian and military environments.

RECOMMENDED RESEARCH ROADMAP

Where do we go from here?:

In broad strokes, the research focusing on Advanced Devices needs to be guided by several key considerations. They include first and foremost improving patient safety and clinical outcomes (in part by recognizing and reducing errors); cost effectiveness; interoperability and standardization of interfaces, plugs, architecture; coherent integration of various components of devices, OR platform, IT; optimizing ergonomics at every level of design.

Important Research Areas:

1) There should be a strong research program with the umbrella title of "smart devices/instruments". Specific areas of focus could then be further categorized as follows:

a) Tactile feedback component – force feedback research undertaken by robotics labs/programs/companies should be mined. Divergent approaches from these various stakeholders have yielded novel solutions to aspects of the surgeon's problem of diminished tactile feedback with MIS. Research into the application of MEMS technology to this problem should occur in parallel. As well as the emerging field of membrane research should be explored for the same purpose.

b) Degrees of Movement Component – once again inroads have been made in this area by the roboticists. Research now needs to be focused on the development of more flexible, lighter, less expensive and mobile, robotically assisted (hand held) devices. Research in this area should be further divided into focusing on the actuator/hand piece and the end effector. Interestingly some of the greatest contributions in this area (though for very different applications) have come from groups that have never been considered potential collaborators, specifically the "animatronics" experts from Hollywood and the Bay area. Research building upon their work should focus on more in intuitive and ergonomic means by which to actuate the surgical end effectors.

c. "Smart Sensor" Component: Research in this area should focus on the harnessing of existing technology and imaging modalities such as ultrasound and Infra Red and exploration of new technologies to equip end effectors to provide intraoperative guidance and error avoidance. Once again MEMS and new membrane technologies should be researched for potential application to the problem.

2) There must be a research program focusing on the incorporation of image-guided techniques and other image data directly into "smart instrument" design and end-effector response.

3) In a related, yet separate vein there must be a research program focusing on **image processing**. The purpose of this work would be to extract maximum and optimal data from digital patient images and to then render altered/enhanced images in real time.

4) Research focus on small/smart catheters and endoluminal devices (vascular and gastrointestinal).

5) Research focus on wireless collection of patient physiologic data and subsequent real time integration of physiologic data with demographic data and previous medical history. Smart systems using machine learning techniques should be designed to continuously monitor the data stream and notify providers of high-risk situations for errors.

6) There must be a strong research program in ergonomics interdigitating with the above areas of research and yet running parallel to them. This very key element of OR (present or future) function is often over looked. Ergonomics studies need to be undertaken at several levels from instrument hand piece design to construction of the integrated OR.

Whereas the areas itemized above comprise the big picture and more long-term goals of Advance Devices research, several short term steps or objectives need to be realized:

1) A standards conference including input from the main industry stakeholders and researchers in instrument design, robotics and imaging and information technology needs to be organized early in this process.

2) Research or data collection focusing on work that is being done or may have been done in fields related to that being targeted is crucial to avoid "reinvention of the wheel". As noted earlier looking at fields as remote as the entertainment industry may be fruitful and ultimately time saving.

3) Once the baseline data has been adequately collected and under the direction of the overall "umbrella" project coordinator, working groups will need to be assembled. These will be multidisciplinary groups, comprised of clinicians, engineers (Biomedical, Mechanical, Electrical, Computer) and programmers to focus on a specific problem or component of the bigger project.

POTENTIAL COLLABORATORS

There are fairly well established forums for communications among researchers at academic institutions in the above mentioned areas However, improved information sharing between industry, the military, and academic institutions would accelerate progress in reaching the goals outlined above. Government agencies such as NIST and the FDA should be consulted and involved in funding development efforts. The VA hospital consortium as well as various Academic Health Centers consortia, need to be informed of the goals of this project. Ultimately, it is these groups' purchasing power that will force the adoption of a universal standard (or set of standards) for device connectivity. Major interdisciplinary programs exist at the following institutions:

CIMIT, Johns Hopkins University, Carnegie Mellon University-University of Pittsburgh, Stanford University, and University of Kentucky. Leaders from these programs in conjunction with DOD leaders should work to influence the national agenda so that appropriate funding is available. In an ideal scenario, a "symatech" model could be created which would allow industry participation in the development and dissemination of new concepts and standards that would benefit all parties.

Operating Room of the Future
Setting a Research Agenda on Telemedicine for the OR of the Future

White Paper
Telemedicine for the OR of the Future

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Background:

The operating room (OR) is a place of startling isolation in real-time. Quality indicators, including patient safety, are only assessed in retrospect. Telemedicine is not integral to current OR management, but the basic tools for interaction and collaboration are already available as fiber, computers and imaging devices. However, opportunities for real time collaboration for teaching or consultation are rarely taken. The knowledge and acceptance of telemedicine in surgery is growing. A recent study showed that although only 8% of surgeons regularly use telemedicine, 85% regularly use the web and 58% have integrated services digital network (ISDN) lines in their hospitals.[1] That statistic, combined with the fact that more than half of U.S. households have computers at home, can have far reaching implications.[2] The basic tools to improve patient care and safety are already available and must now be implemented.

Interaction and collaboration are keys to successful patient care and safety. Telemedicine enhances both greatly. Opportunities must be seized to facilitate telemedicine at every conceivable moment in patient care, from surgical education and training to the initial visit to follow-up care at home. Interaction in the OR with external consultants has been shown to be clinically effective. Low band-width (128 Kbps) telemedicine is reliable in evaluating remote surgical cases and the loss of image quality through teletransmission occurs infrequently.[3] The optical environment can be shared for collaboration using the video capture of the laparoscope and transmitting by phone or Internet Protocol (IP). Consultants can clarify anatomical landmarks as an endpoint to validate collaboration.[4,5] Recent work with camera fixations and open surgery has

validated telecollaboration.[6] The OR can also provide information on demand through Picture Archiving and Communications Systems (PACS), telepathology lab systems, Management Information Systems (MIS) or databank access. At Virginia Commonwealth University's Medical Informatics and Technology Applications Consortium (MITAC) laboratory in Richmond, Virginia, telemedicine has allowed real-time Internet consultation in laparoscopic surgery, open surgery, and anesthesia. Real-time collaboration invites meaningful interaction.[4,5]

Telemedicine in the OR of the future may facilitate significantly better outcomes for patients by allowing more effective case management and better allocation of resources. It is estimated that up to 98,000 patients in the United States die needlessly each year as a result of medical and pharmaceutical errors.[7] The information portals that telemedicine provides allow access to vital patient information anytime, anywhere. Starting with the preoperative screening process, telemedicine can allow for careful analysis of patients before they arrive in the OR, allowing surgery to begin without delay. This would allow doctors to be more effective, especially in remote locations, with the information that is available to them in real-time.[8] A team of skilled surgeons, led by Dr. Jacques Marescaux, recently demonstrated the first complete transatlantic remote-control surgery by removing the gallbladder of a patient in Strasbourg, France, with the help of colleagues in New York City, who controlled the surgical robots used to perform the surgery.[9] This was accomplished with a robust and reliable telecommunications link.

Objectives

The OR should be an interactive shared collaborative environment with access to information on demand pertinent to patient care. Reasonable objectives include the following:

1) Share the operation with all those in the OR, including anesthesia and perioperative personnel, and make all surgical procedures optically accessible to all members of the intraoperative team.

2) Share the operative events with collaborators elsewhere, including surgical consultants, anesthesia consultants and technical support people, to address real-time problems. Overall optical capture of the operative event, not just the surgical field, should provide real-time high fidelity optics for distant collaboration. For anesthesia collaboration, the physiologic sensing data and anesthesia flow chart should be readily shared. The patient record should be a data packet, which can be presented to offsite trainees. The events and status of the technical elements and equipment should be sensor captured and transmitted as needed to appropriate technical service sites, allowing manufacturing representatives to advise in real-time, should malfunction be suspected. Furthermore, proper operation of all equipment in the context of clinical realism can be demonstrated to off-site learners.

3) Share the events for educational purposes to train members of the intraoperative team (nursing, anesthesia, and surgery) off-site, but in real-time and in an interactive mode.

4) Capture the essence of the operative care event for subsequent review. The purpose of the review could be teaching, but in the interest of patient safety, the entire sequence of surgical intervention, anesthesia management and performance of technology should be captured much like the black box in aircraft. Should there be an untoward outcome, the event could be thoroughly analyzed, without reliance on memory and paper records to find root causes of error.

5) Extend interaction beyond the OR, to include simple voice, common visual field to voice, activation of information sources and consultation, interactive video with telestrator, and push of information deemed useful by the consultant, and even mechanical interaction through robotics. The consultant must have access to the events in a manner that generates enough confidence in the interaction to allow the consultant to provide specific advice. This would include access to the electronic medical record (EMR), physiologic patient data, optical access and even a consulting glove, which would give the consultant a sense of haptics, temperature, etc.

Recommended Research Roadmap:

These five objectives are tractable in the next three to five years with a robust research agenda. The research agenda must provide the tools and the clinical evidence to support a drastic change in practice. There are eight elements of the research agenda for telemedicine in the OR.

1) There must be a broad range of sensors to capture the essence of the operation and the perioperative events. The sensors could be imbedded in OR equipment to capture electrical or physical events. The sensors might be those currently used for optics or anesthesia. However, for open surgery and overall capture of the OR beyond the operative field, far better optical systems are needed than those currently applied.

2) The OR must have proper broadband fiber to permit importation of text data, images, radiographs, and robotic instructions and to permit exportation of images, mechanical instructions, text, voice and data. It is imperative to prepare the OR with wireless and wired configurations, and to import and export data to a LAN, WAN or general telecommunications. This agenda item will require considerable design consideration.

3) The OR must have proper software to support interaction and data capture and data analysis for real time decision support. Much of the data acquired in the OR are seen only once by the surgeon or anesthesiologist and not recorded. Consistent data capture and software to analyze these data are needed to permit recognition of aberrations and failure to conform to expectation. Also needed are computer data analysis for decision

support and filter software to notify within the OR or activate an alert outside the OR, should the situation move outside present parameters.

4) There must be a strong research agenda to integrate the components of the OR activity into a coherent data set manageable by voice activated robotics and response. The OR is a collection of independent sensors, monitors, energy sources, mechanical assists, etc. It is urgent that ORs become fully integrated electromechanical systems accessible to surgeon management by voice, as well as keyboard interaction or PDA interaction by anesthesia and circulating personnel.

5) The paramount purpose of telemedicine for the OR of the Future is patient safety! The telemedicine efforts should be designed to avoid dangerous situations caused by lack of timely data, and the need for a real time consultant.

6) There must a strong research agenda to generate the protocols for the OR which are similar to other industrial processes and imbedded in the software and hardware of the OR telemedicine feature. This agenda itself is similar to the agenda mentioned in number 4 above, but with a different approach. In identical models, all events leading to an outcome can be considered as a consolidated process line. The integration of OR technology into process line protocols is specific to the procedure, regardless of the technology.

7) There should be a strong research agenda to develop process simulation to build the OR team strengths. Process simulation and practice should permit design of operations in advance through robotics, practice of individual and team skills and practiced interaction with trainees and consultants at other sites.

8) There should be a strong clinical research program to create the evidence base for practical intraoperative telemedicine. The protocols and software must be validated. Financial and clinical outcome data must be compiled, even as these data accumulate from practical intraoperative telemedicine usage.

Who could collaborate on this research agenda?

Extensive partnerships have already been established with a wide variety of industrial sectors, academic institutions, and governmental agencies, both domestic and international. We must continue to expand upon these partnerships and create new ones, including contacts with the software industry, informatics community, and medical device manufacturers. Other relevant collaborators would include clinical environments of medical centers with telemedicine resources, the telecommunications industry, and cognitive psychologists for human factor and training issues. Team members' collaborative investigations should address all of the five objectives and eight agenda items.

References:

1. Demartines N, Freiermuth O, Mutter D, Heberer M, Harder F. Knowledge and acceptance of telemedicine in surgery: a survey. J Telemed Telecare 2000;6(3):125-31.
2. Home Computers and Internet Use in the United States. Current Population Survey Reports. U.S. Census Bureau, Sept 2001.
3. Demartines N, Otto U, Mutter D, Labler L, von Weymarn A, Vix M, Harder F. An evaluation of telemedicine in surgery: telediagnosis compared with direct diagnosis. Arch Surg 2000 Jul;135(7):849-53.
4. Broderick, TJ, Harnett, BH, Doarn, CR, Rodas, EB, Merrell, RC: Real-Time Internet Connections: Implications for Surgical Decision Making in Laparoscopy. Ann Surg; 234(2):165-171, 2001.
5. Russell, KM, Broderick, TJ, DeMaria, EJ, Kothari, SN, Merrell, RC: Laparoscopic Telescope with Alpha Port and Aesop to View Open Surgical Procedure; J Laparoendosc Adv Surg Tech; 11(4):213-218, 2001.
6. Russell KM, Broderick TJ, Kapoor V, Doarn CR and Merrell RC. A novel method for visualizing the open surgical field. (Manuscript submitted to the J Lap Surg & Adv Tech).
7. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human. Building a safer health system. Institute of Medicine, Washington DC. National Academy Press; 1999:22.

References continued:

8. Doarn, CR, Fitzgerald, BS, Rodas, E., Harnett, B., Prabe-Egge, A., Merrell, RC: Telemedicine to Integrate Intermittent Surgical Services in to Primary Care; Telemed J E Health. 8(1): 127-133, 2002.
9. Fields-Meyer T, Calandra B, Lerner T. French Connection. People 2001; Oct 8:103-106.

Informatics - A Catalyst for Operating Room Transformation

Developed for the Telemedicine and Advanced Technology Center (TATRC)
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Abstract

Computers have supported complex clinical ancillary functions such as the laboratory, radiology, endoscopy, and others for many years. Digital computers have been successfully incorporated into specialized clinical instruments to offer advanced digital devices such as fetal monitors, heart monitors, and imaging equipment. But these devices are often not fully integrated with clinical management and operational systems.

Beyond ancillary department applications, the result of almost thirty years of trying to automate the clinical processes in healthcare is large investments in *both* computer systems and paper medical records that have resulted in paper-based, computer-assisted processes of care. This expensive combination of partial clinical automation and archaic paper-based support processes is a major obstacle to improvements in care delivery and management.

There is a significant need to utilize software, informatics, and standards to help manage the operating room and perioperative processes of care. The potential to reduce adverse events, cost of care, and to enhance the quality of care are real and worth attaining.

The focus of this paper is to outline what medical informatics improvements are needed to support improvements in surgical care, to assist in the management of the highly complex operating room and perioperative care process, and to propose research priorities in these areas.

Current State of Technology

The operating room and perioperative process is the core of intense care provided for many patients. The operating room forms the nucleus of mobile military hospitals. There are many examples of leading edge patient care clinical technologies in the operating room, but they are often not integrated with each other or to a core information technology infrastructure. Whether found in civilian or military healthcare, the operating room is a high-cost and high-risk care environment. Many types of cases, multiple surgical specialties, growing use of technology, and the shear number of elements makes the operating room the most difficult environment to manage in healthcare.

The patient, surgeon, anesthesiologist, nurse, case cart, implants, equipment, medications, supplies, and the operating suite must all be synchronized and optimized for the surgical case to be a success. If any required element is late, does not match the need, or is missing, the case will be delayed, the patient can be harmed, or the cost of the case can expand well beyond what is expected or necessary.

Led by the Institute of Medicine, health providers are focused on the issue of patient safety. Data collected by the National Patient Safety Benchmarking Center estimates that 20% of the medical errors / adverse events are related to surgery. [i] "Although anesthesiologists pioneered modern research into the safety of patients, no specialty is immune to error." (Weingart, et all, 2000) [ii] Medical informatics and technology have an important role to play in making the operating room a safer environment.

While there has been impressive use of technology for direct patient care in the operating room, the use of computer software in this environment has been less impressive. Surgeons are surrounded by sophisticated clinical equipment to help operate on, or monitor the condition of patients, but too often struggle to get basic information about their cases. Managers do not have adequate software tools or data to manage and optimize the perioperative care process. Perhaps due to its inherent complexity, the support of the operating room with computer software has not kept pace with the need.

Operating Room Informatics

The lack of modern operating room informatics (ORI) has slowed the pace of innovation in surgery management. While the improvement of clinical devices and equipment has been impressive, the ability to link all surgical technologies and software to help manage the environment has been elusive. There have been many advances in medical informatics in general; but there has been little attention paid to the area of the operating room and the support of clinicians who practice in the perioperative care process.

"Medical informatics is the scientific field that deals with the storage, retrieval, sharing, and optimal use of biomedical information, data, and knowledge for problem solving and decision making. It touches on all basic and applied fields in biomedical science and is closely tied to modern information technologies, notably in the areas of computing and communication." [iii] [Informatics is the "...the study, invention, and implementation of structures and algorithms to improve communication, understanding and management of medical information. The end objective of biomedical informatics is the coalescing of data, knowledge, and the tools necessary to apply that data and knowledge in the decision-making process, at the time and place that a decision needs to be made. " [iv]

Online Perioperative Clinical Knowledge

The creation, management, and use of knowledge in conjunction with computer software is an important component needed to support innovations and improvements in surgical care. Healthcare is changing rapidly, and learning needs to be continuous: what is known about a disease, optimal treatments and outcomes, the care process, what a patient needs, and about how to best accomplish a task.

A dramatically underused tool in the operating room is knowledge-based software. This is software with 'knowledge inside.' Knowledge enabled software delivers much more sophisticated support to clinicians, and software that is inherently flexible. As clinicians fit the classic knowledge worker category, they require knowledge enabled software applications, but have not been getting it.

Examples of knowledge-based information technologies include knowledge bases (inference engines), specialized databases & warehouses, work flow engines, vocabulary components, and artificial intelligence tools. Examples of how knowledge that will help clinicians and support staff in their daily work includes:

- Medication prescribing algorithms for a kidney transplant patient two days post-op with a nosocomial infection
- Drug to drug, and drug to adverse reaction rules
- Scheduling algorithms to maximize the use of surgery suites, medical supplies, equipment, and staff
- Artificial intelligence tools that use clinical algorithms and rules that assess patient data to suggest when patients are candidates for discharge or transfer to step down care units
- Knowledge bases that analyze patient clinical data, laboratory data, and current medications to assess nosocomial infection patterns for alerts, areas of concern, and potential actions
- Surgical scheduling optimization
- Patient teaching content
- Many others…

The software used in healthcare in general, and the operating room in particular does not yet make effective use of online clinical knowledge, or the software technology to create, maintain, and utilize knowledge.

Standards

The most widely used messaging interfaces in healthcare are HL7 standards. In recent years these have been enhanced to support XML internet standards. At a lower level are international standards for internet routing (TCP/IP) and evolving wireless standards (802.11, Bluetooth, and the CDMA and GSM cellular standards). Healthcare systems should support standard TCP/IP networks and any standard wireless protocol, but too often vendor support in this area is lacking. Other standards in healthcare are oriented primarily to data formats for passing multimedia images (DICOM) to support the storage and exchange of clinical images, and are more widely used

The current limited use of standards in healthcare informatics has led to widespread deployment of stand-alone financial and clinical systems, which create significant barriers to functional interoperability and data sharing, while substantially raising overall capital costs and ongoing maintenance of production systems in the healthcare enterprise. The resulting inability to deliver the right data to the right person at the right time causes financial losses, medical errors, and often significant patient frustration during normal operations.

The opportunity for improvement

Saving time, saving money, and saving patients from medical error is highly dependent on automation of specialty workflows that require customized workstations and views for the specialists who work in the OR. The perioperative process should include the functions of the Surgeon, Anesthesiologist, Periop nurse, Surgery technician, Scheduler and Management For many mobile clinicians, desktop workstations are not an adequate solution for patient care. In many cases, physician adoption of automation has been impossible without mobile applications and technologies.

Consider, for example, a low cost approach to medical error reduction. Starfield reported that medical error is the third leading cause of death in the U.S. with an estimated 225,000 deaths/year and medication errors are the largest component of these deaths. An estimated 7000 deaths/year occur from medication errors in hospitals and 106,000 deaths/year occur from adverse drug events (ADEs). Bates et. al. reported that 42% of serious ADEs were preventable and that errors resulting in preventable ADEs occurred most often at the stages of ordering (56%) and administration (34%); transcription (6%) and dispensing errors (4%) were less common. Errors were much more likely to be intercepted if the error occurred earlier in the process: 48% at the ordering stage vs 0% at the administration stage. Leape showed that dosage errors, in particular, were primarily due to the physician's lack of knowledge about the drug or about the patient for whom it was prescribed.

Studies have shown that automating drug orders and administration reduce errors by 60-100% depending on type of medication error and that preventable ADEs cost $4685 and increase length of hospital stay by

4.6 days on the average. Automation of order entry and drug administration is the fastest and cheapest way to reduce medical error and savings will typically more than pay for cost of automation.

Desired Technological State in 3-5 Years

Vision of the future

The promise of Internet standards and technologies is actualized; changing the way citizens and soldiers communicate, shop, bank, access information, fight wars, manage stock portfolios, and interact with a wide variety of people and organizations. Former "Buck Rodgers" technology fantasies become every day reality; where PDAs, digital cell phones, and wireless access to the Internet can transform what is dream-able to what is do-able.

There will be people born in the next five to ten years, who will have the beginning of their life recorded in an electronic medical record and their entire lifetime of illness, broken bones, and checkups will all be tracked and recorded digitally. These future patients will have easy but secure access to their medical record, and will routinely input data about their health and illnesses. As they move from one city to another or one duty post to another, they will be able to approve (online) that their digital medical record can be accessed by their new care provider and turn off the ability of their former care provider to access the record.

The future digital medical records will be accessible by researchers through appropriate security controls, and with patient identifiers removed. Researchers will have dramatically better data from which to plan studies and analyze outcome data. Patients who agree to participate in clinical trials will contribute their de-identified data to be securely abstracted from their digital record and be integrated into clinical study databases and programs or world-wide clinical studies and trials.

Patients and clinicians will interact via the Internet at appropriate events to more quickly and easily perform tasks. Clinicians and patients will choose the best technology and mechanism to interact without regard to barriers for payment or security. Patients will not have to ask for drug refills or follow-up appointments, as reminder systems will track these type of events and trigger actions to be performed, based on online process protocols and patient preferences and pre-approvals.

Massive online teaching content repositories will aid medical education. These repositories will have sample lifetime digital records that allow students to gain insight to symptoms, life style issues, and help them improve their ability to design care and treatments for patients. Digital libraries of clinical images, test results, 3D surgery practice environments, and 'modeling scenario environments' will help students learn diagnosis and treatment. They will also support experienced clinicians in continuing medical education.

Medical students will belong to a 'digital service' early in their training that will have a ward of simulated patients, with simulated pages (requests for help, change of orders, patient requests a pain medication, et cetera), simulated rounds, and events the students will need to react to (before they have to be part of a real service in a hospital).

As a touch point of computer science, medicine, and library science, the field of Medical Informatics will become more important as software and clinical knowledge must be managed synergistically to gain the full power of each.

Technological Opportunities for the Operating Room

In the future, the OR and the perioperative process will be supported by modern computer software with specially tailored online knowledge to optimally link the software to clinicians and specialists. Early implementations of mobile devices for surgeons have eliminated one hour per day of paperwork. Online order entry and drug administration systems have been shown to radically decrease medications errors by the Veterans Administration and others. And charge capture systems have shown a 400% to 700% return on investment in many large institutions, often recapturing more than 10% of charges that never entered the billing system.

Gartner Group and others have shown the life cycle cost of a handheld device is on the order of 20% of workstation costs. Numerous ROI studies have shown that user satisfaction doubles and time to complete many tasks is cut in half with a mobile device vs. a PC. A mobile platform that aggregates mobile clinical

applications on a single device, provides interoperability between applications, and embraces, extends, and enhances previously installed healthcare information systems is the lowest cost solution to reduction of the most serious medical errors in the least amount of time.

Multiple modes of wireless connectivity are now available for deployment in clinical settings. Wireless LAN, cellular phone, and Bluetooth standards for wireless connectivity have evolved to the point where multiple vendors are delivering reliable products. The rate of evolution of mobile devices and wireless modes of connectivity is higher than almost any other area of technical innovation. By the end of 2002, a smart cell phone may get better performance than today's Palm pilots in a wired docking station.

The intersection of web services, mobile devices, and wireless communications advances allows the delivery of the right data to the right person at the right place in a timely manner that was not previously possible. For the first time, it is possible to achieve widespread adoption of computing technology by mobile clinicians who need it to save time, lives, and money. The small form factor of mobile devices combined with wireless connectivity allow them to be introduced into an operating room setting with minimal reconfiguration of current infrastructure. As surgery moves out of the operating room into the outpatient setting, the mobile devices can follow and technology investments can be leveraged.

ORI standards vision
Standards support by healthcare information vendors and information technology staff, particularly for worldwide internet standards, will allow disparate systems to work together much better than in the past. Acquisition, installation, enhancement, and maintenance of these systems will be at lower cost than most current vendor offerings. The amount of available functionality with current systems configurations and the ability to more quickly add new functionality will be significantly increased with appropriate standards support.

Standards which support functional interoperability so that one system can evoke functionality in another system will deliver the most functionality and highest quality data, at the lowest cost. Standards which support data sharing, usually through messaging interfaces, are expensive to implement and maintain and present a barrier to effective intersystem communication. In addition, the number of messaging interfaces required increases far more rapidly than the number of heterogeneous systems intercommunicating producing an interface explosion in a large enterprise.

In another dimension, adherence to global standards will produce more interoperability at much lower cost than adherence only to healthcare specific standards. Global standards allow component based systems to be built using a wide variety of commodity components. Healthcare standards are supported by specialized systems and devices with far less functionality at much higher cost than commodity products.

Global and Healthcare Standards Comparison

Standards	Global	Healthcare
Functional integration	WSDL XML SOAP	Vendor specific XML objects
Workflow	OMG jFlow	"Big Workflow"
Messaging Interfaces	XML	HL7 MIB
Communications	TCP/IP 802.11 Bluetooth CDMA	DICOM

At the highest level, the biggest return in time, functionality, and dollars comes from widespread support of global internet standards. These include the emerging World Wide Web Consortium (W3C) Web Services Description Language (WSDL), which defines how to support XML/SOAP based integration of heterogeneous systems. These and other W3C standards are leveraging business-to-business

communications globally and are the technology of choice for accelerating healthcare system interoperability. Several vendors in the healthcare industry provide XML component interfaces at various levels of compliance with W3C standards, notably PatientKeeper, Cerner, and IDX.

The next level of interoperability are workflow standards which allow specification of the steps of a business process and managing both humans and machines to assure proper execution of the process independent of any particular information processing system. The Object Management Group serves as the international standards body for Workflow Management Coalition (WfMC) specifications and has currently adopted the jFlow standard as the approach to integrate multiple disparate workflow engines. In the healthcare industry, there are no adopted workflow standards. However, the current leading design candidate for internet-distributed workflow that manages business processes across disparate systems was developed in the healthcare industry. (Sutherland and Alpert, 1999)

The transition to knowledge based technologies
In the 1960's when hospitals first purchased a mainframe computer they paid a lot of money for the hardware, but the application software was considered free. An example of this would be the Shared Hospital Accounting System (SHAS) offered by IBM during this time period.

When a hospital or Integrated Delivery System invests in a computer system today, the total cost of hardware such as an NT server, Win98 microcomputers, and network components is relatively low. Meanwhile, the cost of software and ongoing maintenance is far from free. For large healthcare organizations, investments in the range of twenty five to fifty million dollars are not uncommon for a full suite of clinical, operational, and financial software applications, with ongoing annual maintenance costing of fifteen to twenty per cent of the initial investment.

Sometime in the not too distant future, healthcare providers will license the "x" version of optimized and integrated healthcare knowledge to operate and manage their care delivery organization, and the hardware and software to use the knowledge will have a relatively low cost or will be provided at no cost when knowledge is licensed. Access to proven online clinical knowledge and its ability to optimize care and operational processes will become the reason clinicians use computers.

The future of Operating Room Informatics
Building on the existing foundations in informatics and computing, a new focus will be created on the operating room and the perioperative process.

An initial group of interested parties eventually expands into an Operating Room Informatics (ORI) international work group. Technology and online clinical knowledge standards are created and supported.

Emulating the success of the Radiological Society of North America (RSNA), ORI becomes a catalyst and integrating force for technology and informatics advancement in the operating room and the perioperative care process.

Technology vendors collaborate around ORI standards. Clinicians and specialists collaborate to create online clinical knowledge that makes software 'smart' and dramatically more valuable. Managers utilize information and online knowledge to enhance the operations of the OR and supporting units, reducing costs and decreasing cycle times.

The ORI effort is supported by and utilized by United States military, the VHA, and civilian clinicians and care facilities. The impact of these three groups working together on ORI enhances the depth and quality of ORI knowledge and standards, and increases the value of ORI to all parties.

The synergy created by ORI has a material positive impact on the care and effectiveness of surgical procedures and follow-on care in the United States. Patients are safer, care is demonstrably better, costs are lower, and patients are more satisfied with the care when they receive treatment at a facility where ORI has been used to manage and improve the perioperative process.

Recommended research areas in Operating Room Informatics

1. OR User Interface

Design and test the optimal User Interface (UI) for surgeons, anesthesiologists, and nurses to input and access clinical data. The optimal UI will support multi-mode access, where clinicians are able to use Mobil devices (such as the PDA or tablet computers), Internet browser access to Intranets, and adequate remote access through secured Internet connections.

2. OR usability laboratory and test process

Create an Operating Room usability test process. This would form the basis to test technology of all types (especially computer software, user interface, online clinical knowledge, and information technology) prior to actual use for patient care. This effort would include the construction of both actual and virtual (through network connections and simulation) test laboratories to manage and conduct tests. Time and motion studies should be utilized to create the testing scenarios required. Test scenarios will need to be created and maintained. Testing software will support the use of test scenarios. Statistical analysis functionality will be required to ensure the outcomes of tests are fully analyzable.

3. Online clinical OR knowledge

The "knowledge inside" of clinical software is the missing catalyst needed to spark the innovation in the operating room. Knowledge based software have a number of value propositions:

- Reduce errors in the provision of service and care
- Support the collection of sophisticated clinical outcome information to support analysis of ongoing care and of new procedures and treatments
- Support the definition of best practice and a methodology to positively impact daily work and tasks to follow best practice (make the best way to perform a task also the easiest way)
- Record and act on patient and customer preferences
- Support cost reduction in service and care processes by utilizing knowledge that has been thoughtfully created
- Reduce rework not only by delivering better access to information but also linking information and knowledge
- Optimize modeling software to manage, plan, and predict the complex surgical process (like aircraft routing algorithms)
- Allow staff new to a job or process - still in the timeframe of being trained, to be more quickly effective in their roles, as proven knowledge guides the way they perform tasks

Create knowledge editing tools and processes. Support a 'virtual knowledge factory' linking clinicians from across the world to participate in creating and reviewing online clinical knowledge.

4. ORI Standards

Create a straw man of what standards are required to support innovations in the operating room and preoperative process. Perform a meta-analysis of healthcare standards to identify and assess the gap between the needs identified and what standards are defined as currently.

5. Long-term OR clinical outcomes study of the effect of informatics and Information Technology on the Operating Room and perioperative care process

Utilizing new models for software applications, OR clinical vocabularies, and OR online clinical knowledge, support the long-term study of perioperative care with a sophisticated outcome study project.

Collect data from many OR cases from around the world in civilian, military, and Veterans hospitals. Utilize modern ORI techniques and technologies to create a comparative database to store and support analysis of perioperative documentation and key clinical measurements to facilitate the review and improvement of care, processes, and online knowledge

6. Analysis of ORI vocabulary requirements
Partner with current clinical vocabulary providers to assess the needs of the operating room and perioperative process for vocabulary support. The outcome of the assessment could be to create a new clinical vocabulary for the operating room, or to suggest modifications to current vocabularies to better support the operating room of the future.

Work with the National Library of Medicine and Apelon to incorporate any new or modified OR vocabularies into the NLM's Metathesaurus.

7. Optimized Process Definitions for the perioperative process
Create a work group to assess and create a generic 'starter set' of process maps and work flow engine 'definitions' for perioperative processes. Contribute this process centric knowledge and documentation to the public domain. Teach and lobby healthcare software vendors to utilize this knowledge in new versions of Operating Room support software applications.

8. Design the optimal IT infrastructure for the operating room and perioperative process
Dedicate Information Technology experts from military, the Veteran's Administration, and civilian healthcare to form a review team to assess the IT infrastructure requirements for operating rooms. The group would then compare this defined need with what is currently available in operating rooms and define the gap.

The group should document the gap, and create a document (that could become a standard) of the IT requirements for operating rooms of the future. IT infrastructure includes; servers, client hardware, security, redundancy, processing capacity, networks (wired and wireless), and technology management tools & processes.

9. Design and test new informatics / information technologies for the operating room
Convene a conference and then a work group to identify current or new informatics technologies that would be used in the operating room of the future.

These technologies may include (and others);
- Patient identification / tagging to support automated patient tracking
- Linkage of OR management software applications to surgical robots
- Other

10. Operating Room clinical Documentation Standards
From the foundation began by some groups (such as the AORN's Perioperative nursing data set (PNDS), define a complete set of standards for perioperative care documentation. This should include all caregivers in this area (surgeons, anesthesiologists, RNs, others).

Publish the new documentation standards. Seek to have all software vendors support and utilize the standard. Provide training, updates, and other techniques to keep the standard current and relevant.

11. Create a national 'operating room network' (ORNet)
Design optimal technologies and methods to enhance real-time communications between clinicians in the operating room. Gather telemedicine experts, vendors, and test-site operating rooms to define standards and options to create a standard network to link all operating rooms together via telecommunications and other technologies and approaches.

Create a national 'operating room network' (ORNet) to link civilian, Veterans Administration, and military operating rooms together to facilitate care, research, teaching, and mutual assistance during disasters and bio hazard events.

Conclusion

Given the complexity, cost, and importance of the care provided in the operating room and perioperative process, it should be a focus of medical informatics and software development.

As a touch point of computer science, medicine, and library science, the field of Medical Informatics will become more important as software and clinical knowledge must be managed synergistically to gain the full power of each.

Summary of Proposed OR Informatics Research Areas

1	OR User Interface
2	OR usability laboratory and test process
3	Online clinical OR knowledge
4	ORI Standards
5	Long-term OR clinical outcomes study of
6	Analysis of ORI vocabulary requirements
7	Optimized Process Definitions for the perioperative process
8	Design the optimal IT infrastructure for the operating room and perioperative process
9	Design and test new informatics / information technologies for the operating room
10	Operating Room clinical Documentation Standards
11	Create a national 'operating room network' (ORNet)

References

Senge, Peter M., The Fifth Discipline, The Art & Practice of The Learning Organization. Currency Doubleday, Copyright (c) 1990. Pages 5-6.Senge P, The Fifth Discipline

Safety-Centered Solutions. (March 21, 2001) Surgical errors most frequent and costly medical errors. http://www.sccare.com/news/articles/pr-03-21-01.html

Quigley A., Beyond the double doors. New generation surgical information systems. MD Computing, 2000 Sep-Oct;17(5):29-32.

Parker JL, Abbott PA., The new millennium brings nursing informatics into the OR. AORN J 2000 Dec;72(6):1011-7

Sandrick, K., Virtual reality surgery: Has the future arrived?. CyberSurgeon, Volume 86, Number 3, March 2001, Bulletin of the American College of Surgeons

Rosendale, D, MD, Surgical Informatics: An application of Health Informatics. The Informatics Today, e-journal of Biomedical Informatics, Vol.1, No.2, February 2002.

Burgert O., Gockel T., Giesler B., Dillmann R., Comparison of tracking techniques for intraoperative presentation of medical data using a see-through head-mounted display. Stud Health Technol Inform 2001;81:443-5

Sandrick, K., Effective online CME: It's only a matter of time. CyberSurgeon, April 2000 Bulletin of the American College of Surgeons

VCU Conducts First-known Anesthesiology Via Internet. Virginia Commonwealth University Health System: News. January 14, 2002

Gilder RE., Koch F., McBride S., Enhancing perioperative nursing effectiveness through informatics. AORN J 1999 May;69(5):978, 981-2, 987-7.

McDonald G., Monosky A., Montali M., Surgical Informatics Is a Useful Management Tool. The American Journal of Surgery, Volume 174, Issue 3, September 1997.

Sandrick, K., Internet broadens surgical education environment. CyberSurgeon, Volume 86, Number 8, August 2001, Bulletin of the American College of Surgeons

London, R. MD, One Doctor's Wish List: Anesthesia services move into the computer world. October 1997, Healthcare Informatics

Web Services Description Language (WSDL) 1.1
http://www.w3.org/TR/wsdl

Sutherland J. and Alpert, S. "Big Workflow" for Enterprise Systems. OOPSLA Workflow Workshop Proceedings, 1999.

Links to Standards Organizations

Object Management Group
http://www.omg.org

Workflow Management Coalition
http://www.wfmc.org

HL7
http://www.HL7.org

Bluetooth SiG, Inc.
http://www.bluetooth.org

Institute of Electrical and Electronic Engineers IEEE
802.11 wireless networking, and the medical Information Bus (MIB) standards
http://www.ieee.org/portal/index.jsp

Internet Engineering Task Force (IETF) – standards for TCP/IP
http://www.ietf.org/

American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) standard for the Digital Imaging and Communications in Medicine (DICOM)
http://medical.nema.org/

W3C
Web Services Description Language
http://www.w3.org/TR/wsdl

W3C
Extensible Markup Language (XML)
http://www.w3.org/XML/

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Minear has worked in the healthcare industry for over twenty-three years. He is a graduate of the University of Iowa. He currently holds the dual role of corporate Senior Vice President and CIO for the University of Maryland Medical System (UMMS) and CIO for the University of Maryland Medical Center.

Minear has previously held the positions of Vice President and CIO at Park Nicollet Health Services, CIO of the University of Minnesota Hospital and Clinic, Vice President at Medicus Systems, and others. While at Medicus, he co-designed and managed the development of the first commercial Executive Information System for healthcare (DISCOVERY EIS).

He has been a frequent speaker at health industry forums and meetings such as the Healthcare Information and Management Systems Society (HIMSS), Radiological Society of North America (RSNA), American Health Information Management Association (AHIMA), the Medical Group Management Association (MGMA), and the Gartner Group technology conference.

Minear is an Associate faculty member at the Johns Hopkins University Bloomberg School of Public Health, where he teaches the graduate course 'Health Management Information Systems.' He has taught seven courses for the College of Healthcare Information Management Executive's (CHIME), Information Management Executive (IME) classes.

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Dr. Sutherland is a Distinguished Graduate of the U.S. Military Academy and has advanced degrees from Stanford University and the University of Colorado School of Medicine. As past Secretary of the ANSI X3H7 Object Information Management Technical Committee, he was liaison to the X3H2 SQL Database Committee, and Chair of the Joint Committee of X3H7/X3H2 and ODMG (Object Database Management Group). He has been the Object Databases, Easel Corporation, VMARK Software, and IDX Systems Corporation representative to the Object Management Group and a former board member of the Smalltalk Industry Council. His work as Chair, OOPSLA 95/99 Workshops on Business Object Component Implementation and Design has helped to facilitate research into object-oriented architectures for enterprise object systems.

Endnotes

[i] "The National Patient Safety Benchmarking Center is a data repository of adverse events culled from various hospitals and 300,000 patients. SafteCare Systems, Boston, collects and analyzes the amassed data." Chapman N, From Behind Closed Doors, Healthcare Informatics, November 2001, © 2001 The McGraw-hill Companies, Inc.

[ii] Epidemiology of medical error, Weingart,S., Wilson R., Gibberd R., Harrison B., BMJ Volume 320March 18, 2000 – Further citation for this passage to Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthiology 1984;60:34-42.

[iii] Columbia University Informatics web site - http://www.cpmc.columbia.edu

[iv] Internet FAQ Archives - http://www.faqs.org/faqs/medical-informatics-faq/

Setting a Research Agenda on Patient Safety in Surgical Settings

White Paper

Developed for the

Telemedicine and Advanced Technology Research Center

US Army Medical Research and Materiel Command

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Setting a Research Agenda on Patient Safety in Surgical Settings

On November 8 and 9, 2001, leading experts in patient safety, medical informatics, advanced surgical devices, telesurgery, and surgical facilities met to formulate strategic directions for "OR of the Future" in both military and civilian healthcare. Co-hosted by the University of Maryland Medical Center and the Telemedicine and Advanced Technology Research Center (U.S. Army Medical Research and Materiel Command), researchers, surgeons, and experts in the field of operating room technology addressed the current state of research and technological developments. Experts in patient safety, medical informatics, advanced surgical devices, telesurgery, and surgical facilities met in focused work groups to develop a proposed research agenda for each content area. This summary provides an overview of the proposed agenda related to patient safety in surgical settings. It was developed by clinicians, researchers, and patient safety experts who comprised the patient safety work group.

Background of the Problem

Clinicians caring for surgical patients strive to ensure patient safety while providing quality care. However, existing evidence suggests that both medical and surgical errors are excessive in the current health care system. A particular

concern is the fact that "surgical errors often appear the worse....The end points in surgery are often more concrete and immediate than in medicine – survival or death, cure or failure" (Hettiaratchy, 2001, p. 887). Limited information exists regarding the exact incidence and nature of surgical errors and adverse events, and even less is known about actions and interventions that promote and ensure patient safety.

The Institute of Medicine (1999) estimated that between 44,000 to 98,000 deaths occur annually as the result of medical errors including medication errors, surgical mistakes, and surgical complications. Reports such as this one provide some insight into the problem, however significant knowledge gaps remain. This is further confounded by inconsistent research designs, methods, and reporting frameworks.

Inpatient surgery and postoperative care appear to significantly contribute to adverse events. An analysis of 15,000 nonpsychiatric hospital discharges revealed that 66% of adverse events were found to be related to surgery. Adverse events included technique-related complications, postoperative bleeding, postoperative infections, medication-related injury, and deep venous thrombosis. These researchers reported that adverse events accounted for 12% of all hospital deaths (Gawande, Thomas, Zinner, & Brennan, 1999). In a subsequent report, Canadian researchers reported that 39% of patients suffered a total of 144 complications when they examined 1277 patient-days for 192 general surgery patients. Two of these complications were fatal, and ten were

life-threatening. Seventy-eight percent of the errors occurred during or after surgery (Wanzel, Jamieson, & Bohnen, 2000).

Even less is known about adverse events for patients undergoing outpatient surgery, ambulatory, or office-based surgery. Furthermore, there are no widely accepted or used standard definitions for these various settings making data comparisons difficult if not impossible. Grazer and de Jong (2000) provided some insight into the problems associated with outpatient or ambulatory surgery when they reported mortality rate for liposuction as 19.1 per 100,000. A recent JCAHO Sentinel Event Alert that reports that 58% (n=87) of wrong site, wrong person, or wrong procedure cases have occurred in ambulatory settings (JCAHO, 2001). With the ever increasing volume of surgeries in settings outside of the hospital, these remain critical areas for further evaluation and analysis.

An analysis from the National Patient Safety Benchmarking Center, Safety-Centered Solutions, Inc, reports that the five most costly adverse event categories are surgery, nonsurgical treatment, nosocomial infections, medication errors, and pressure ulcers. These adverse events accounted for 81.5% of the total costs in their database. The most common adverse event categories in the database were surgery (20%), medication errors (16%), nonsurgical treatment (14.8%), patient falls (8.8%), and nosocomial infections (7.5%) (Safety-Centered Solutions, 2001).

These data provide an imperative for surgical professionals to actively address errors that result in adverse events while developing systems that

ensure safe care for all surgical patients. To intervene appropriately, an understanding of the nature and incidence of adverse events related to surgery must be developed. Furthermore, actions that minimize the risks to surgical patients must be identified, implemented, tested, and evaluated.

Work Group Vision: This work group viewed safe care as a pre-condition and first priority for both patients and their caregivers in surgical settings. The group believed ensuring safety was consistent with patient-centered care and achieving optimal outcomes. The group recognized that the majority of errors result from poorly designed systems and clinical processes, and are not the fault of individual clinicians.

The First Consulting Group's Patient Safety Model served as the unifying framework for a research agenda related to patient safety in surgical settings for the next three to five year period. The group established three overriding principles that provide the foundation for this research agenda: 1) quantifying and measuring adverse events, 2) focusing on adverse events, rather than medical errors; and 3) guiding the process with existing knowledge.

Quantification and measurement provide the framework so as to identify the actual incidence and prevalence of adverse events across the surgical continuum. These data will assist in efforts to determine the economic costs of adverse events and the cost-effectiveness of interventions to promote and ensure safety. Focusing on events that actually result in patient injury will provide information that can readily improve outcomes and reduce costs. Errors

and near-misses that do not result in actual injury should provide a secondary focus and contribute to a subsequent research agenda.

Critical to the research agenda related to safe patient practices in surgical environments, we must first: 1) identify research gaps, 2) implement evidence-based practices, and 3) understand the future implications for safety. Additionally, consideration must be given to human factors and safety research in other clinical and industrial settings including aviation. To achieve this goal, integrative research reviews and meta-analyses must be conducted and made available to surgical clinicians and researchers so that subsequent practice changes can be evaluated.

Recommended Research Agenda

Seven key components provide a focus for this research agenda for safe care for surgical patients. Concentrating on these specific areas will generate an understanding of the nature and incidence of adverse events in surgical settings. The intent is to develop new knowledge by building on current knowledge related to human factors and error reduction strategies. With patients' lives at risk, the priority of a research program related to adverse events and safety is clear.

1) **Governance and Leadership:** Research within clinical environments will provide critical understanding about the relationship of leadership and safe practice in surgical settings. Little knowledge exists about the type of leadership and administrative support that must be present to create a culture of safety. It

is unclear at what levels that support must be provided and whether every clinician must have certain leadership qualities and abilities.

In surgical settings, it is unclear which clinician(s) has/have the ultimate authority and responsibility for patient safety and how hierarchy related to status influences safe practice. Little is known about the most effective management strategies and approaches required to ensure safe clinical practices. Furthermore, clinicians lack reliable and valid information about how safety becomes the primary focus or precondition and how a culture of safety is infused throughout clinical environments.

There are a number of research questions that must be answered. Information derived from such a program of research will provide managers and leaders the requisite knowledge to lead clinicians in safety initiatives. Key questions regarding leadership and governance include:

a. How does leadership determine and create a culture of safety?
b. How do leaders promote the vision of safety more broadly?
c. How do leaders promote a non-chaotic operating room environment?
d. How do leaders influence the culture of safety?
e. How can safety be promoted to key leaders and administrators?
f. How can managers and leaders create an environment where errors are readily reported and the information derived from error reporting is used to improve clinical practice?

g. What incentives and resources to promote safety should managers and leaders provide?

2) **Culture of Safety:** The factors that contribute to safety in healthcare remain poorly understood. Numerous experts suggest errors and adverse events are the direct result of system failures, a lack of teamwork, and communication problems. Research that explores how the attitudes and behaviors of individuals and teams interface with organization norms and influence health outcomes will provide critical new information.

To address these issues and others, the numerous, simple and complex systems within surgical settings must be extensively studied. Understanding how to create and maintain a culture of safety in surgical settings is crucial to any safety initiatives. Information derived from this research will support best practices and help create safe and effective processes.

Topics of high priority include research projects related to promoting high performance teams, supporting teamwork, and enhancing effective communication. A better understanding of verbal and non-verbal communication and how it is used in surgical settings will assist professionals to effectively communicate. For example, positive and effective interactions with professionals, specialists, patients, and families will obviously support and enhance a culture of safety.

Critical to the reduction of adverse events is identifying effective environments for the education and training of health care professionals in

surgical settings. Additionally, criteria for evaluating the aptitude of individuals applying to professional programs must be developed and implemented. Setting uniform standards will ensure that only applicants with the appropriate aptitude and attitude are enrolled in professional programs. Concurrent with this effort, strategies to evaluate the skills and abilities of students in clinical settings must be developed and implemented. Learners who demonstrate unsafe practice or mediocre performance must be identified. If these issues can not be adequately addressed by remediation and further education, these individuals must have their practice restricted.

3) Define Objectives: The most obvious and pressing needs are to obtain comprehensive, reliable, and valid data about the incidence and nature of adverse events in surgical settings. For example, the Colorado/Utah study reported that 30% of adverse events in surgery were related to technical considerations. However, from this report it is unclear what type of error constitutes a technical consideration. A better understanding of the true nature of adverse events will provide a focus to the overall research agenda and specific programs of research. The data critical for patient safety in the operating room must be identified, collected, analyzed, and used to improve clinical processes and systems.

4) Design Safe Process: Identifying and designing safer and more effective clinical processes serves as a primary research focus. The design of safe practices can not occur in isolation from existing knowledge. Initially, organized

efforts should focus on assembling the relevant research and literature and disseminating evidence-based recommendations for clinical processes and safe practices. Clinical processes can be significantly influenced by creating, disseminating, and implementing evidence-based protocols. Such guidelines can provide a foundation for re-designing clinical processes and thus improve patient safety.

Examples of safety-focused clinical practice guidelines would include preparing patients for surgery, patient identification, ensuring the correct site for surgery, handling of extraneous objects (instruments, sponges, needles, etc.), and recognizing patients at high risk for postoperative complications. An understanding of the best use of information technology in the provision of safe care must be determined. Technology designed to assist clinicians may be fraught with error potential. A better understanding of how technology can provide useful feedback to both clinicians and students will support a culture of safety. Clinicians and managers need improved quantification of which factors contribute to safe processes. Technology may provide the means to monitor and quantify specific types of clinical events by recording and analyzing clinical processes.

5) Process Implementation: Clinicians, managers, and researchers need a better understanding of the factors critical to process implementation. It is unclear why surgical settings have failed to implement innovations and improvements that have been demonstrated to improve patient safety. One

research priority is developing an understanding of clinical environments in surgical settings that are most conducive to adopting improvement.

Also, very little is known about what type of feedback is helpful, how to best provide it, and how the use of feedback can improve safety. It is unclear why patient safety information in the surgical setting has failed to be organized, consolidated, or disseminated in a systematic manner.

6) Measure and Monitor: Despite the availability of multiple data sources about adverse events and errors in the operating room, it is unclear if these sources provide the required information to assist clinicians, managers, and researchers in promoting safety. To date, the critical data elements required to measure or predict safety in surgical settings have not been determined.

Also, no one has identified critical factors that require constant vigilance in the operating room. If these factors could be identified, negative outcomes could be minimized, if not avoided entirely. Key research initiatives include identifying data sources, establishing the critical data elements, and determining the most efficient and reliable methods of capturing pertinent clinical data.

7) Creating a Learning Environment: The establishment of a learning environment should be considered the biggest challenge for creating safe practices in the surgical setting. Little knowledge exists that provides an understanding of how to inform clinicians and thus change clinical processes when new information or research findings are available. Research programs that examine the creation of a learning environment in surgical settings will provide

the framework for future successes. Knowledge derived from such efforts will assist in process changes and ongoing improvements in practice.

Specific challenges remain in terms of developing educational systems that provide timely and pertinent feedback that promotes safe practice. An understanding of how to successfully teach teamwork and collaboration earlier in professional programs must also be established. Additionally, numerous research questions must be addressed early in the research agenda.

1) What are the most effective instructional methods to teach teamwork and collaboration?
2) What instructional methods promote safe clinical practice?
3) What are the most effective dissemination methods?
4) What are students' and residents' beliefs about patient safety and medical error?
5) What are the most effective strategies to accelerate learning?

Conclusions: The synergy of effort by numerous individuals and groups will be required to achieve these specified objectives and implement this ambitious research agenda. Collaborations will be required with groups such as the American Hospital Association, AORN, American College of Surgeons, the American Society of Anesthesiologists, and other stakeholders. Multidisciplinary expertise from the clinical and managerial sciences will be a prerequisite to any research endeavors. Epidemiologists, medical anthropologists, and psychologists are a just a few of the potential partners in these efforts. With approximately

80% of all surgeries and invasive procedures performed in outpatient settings, all types of clinical environments must be examined to promote safety. Settings should include office-based, ambulatory, inpatient, community, teaching, rural, and urban healthcare facilities.

Research provides the framework that will contribute to and ensure patient safety in surgical settings. With patients' lives at risk each day, safety research is of the highest priority. Priority areas for research efforts include: 1) determining the actual incidence and nature of adverse events across the surgical continuum in all types of surgical settings, 2) understanding the operating room as a functional unit, 3) evaluating work design and its relationship to improving safety, 4) understanding how accidents occur in complex surgical environments and systems, 5) exploring the relationship of communication to adverse events, and 6) determining the relationship of human factors to safety problems in these settings.

The value in research will be providing new knowledge and understanding to clinicians in surgical settings. Additionally, resources will be required to support clinicians in their efforts to provide quality care. Research that is not utilized by clinicians to improve the safety of surgical patients will have limited value. The need for research that contributes directly to patient outcomes has never been greater. Surgery should be a safe experience for all patients. Every patient deserves to have the right surgery, on the correct body part, and with

minimal preventable risks. Patient safety across the surgical continuum regardless of the setting is the ultimate goal of these research efforts.

REFERENCES

Gawande, A. A., Thomas, E. J., Zinner, M. J., & Brennan, T. A. (1999). The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery, 126(1), 66-75.

Grazer, F. M. & de Jong, R. H. (2000). Fatal outcomes from liposuction: Census survey of cosmetic surgeons. Plastic and Reconstructive Surgery, 105, 436-445.

Hettiaratchy, S. (2001). Uses of error: Surgical mistakes. Lancet, 358, 887.

Institute of Medicine. (1999). To err is human: Building a safer health system. Washington, DC: National Academy Press.

JCAHO. (2001, December 5). A follow-up review of wrong site surgery. Sentinel Event Alert, 24.

Safety-Centered Solutions. (2001, March 21). Surgical errors most frequent and costly medical errors. http:www.sccare.com/news/articles/pr-03-21-01.html (accessed 11/19/01).

Wanzel, K. R., Jamieson, C. G., & Bohnen, J. M. A. (2000). Complications on a general surgery service: Incidence and reporting. Canadian Journal Of Surgery, 43, (2), 113-117.

Setting a Research Agenda for Perioperative Systems Design

White Paper

Developed for the

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Background

On November 8 and 9, 2001, leading experts in patient safety, medical informatics, advanced surgical devices, telemedicine, and surgical facilities met to formulate strategic directions for the "OR of the Future" in both military and civilian healthcare. Co-hosted by the University of Maryland Medical Center and the Telemedicine and Advanced Technology Research Center (U.S. Army Medical Research and Materiel Command), researchers, surgeons, and experts in the field of operating room technology addressed the current state of research and technological developments in several content areas, including Telemedicine, Advanced Devices, Patient Safety, Informatics and Perioperative Systems Design. This summary provides an overview of the proposed research agenda related to Perioperative Systems Design.

The original intent of the work group assembled to create this white paper was to focus on the surgical work space and the work processes that occur therein, i.e. how the physical infrastructure supported surgery. This scope proved to be less than satisfactory in complimenting the work of the four other focus areas. Consequently, the work group on several occasions redefined its mission. What arose was a broad set of issues integrated under a research framework we identified as Perioperative Systems Design.

Perioperative Systems Design describes a rational approach to managing the convergent flow of patients having procedures from disparate physical and temporal starting points (frequently home), through the operating room and then to such a place and time (e.g., home or hospital bed) where future events pertaining to the patient have no further impact on OR operations. This process for an individual patient can be envisioned as a nested set of timelines: a coarse-grained timeline beginning with the decision to perform an operation and ending when the patient definitively leaves the post-op experience, and a fine-grained timeline encompassing the immediate pre-op, intra-op and post-operative course. At each point, physical infrastructure and work processes impact the progress of patients along these timelines. Starting from this construct, Perioperative Systems Design can be conceptualized, studied and optimized like any industrial process in which many materials, actors and processes are brought together in a coordinated workflow to achieve a designed goal.

In this white paper on Perioperative Systems Design, we will present the current state of the art and technology with respect to the perioperative process. We will develop the notion of nested perioperative timelines, which illustrate how unexpected events pertaining to one patient have effects that propagate downstream and frequently affect global OR efficiency. We will set out a desired state of Perioperative Systems Design for the OR of the Future. Next, we develop a research roadmap (essentially a set of specifications) for future research in Perioperative Systems Design. Finally, we will set forth a research agenda for accomplishing the desired-state goals.

Current State of the Perioperative Systems

Perioperative Systems Design in today's OR involves a complex interaction with (and often reactions to) physical infrastructure, changing technology and human factors. Hospital processes are often defined by facility design which is an architectural discipline rather than a production system design discipline. Once hospital facilities are built the processes they 'support' are hardwired and difficult to change. Often processes remain locked in for decades due to the capital investment required to make changes. New technology has been introduced primarily for intraoperative use, not focused on pre- or post-operative processes

or aimed at infrastructure improvements. Often, new technologies actually disrupt the perioperative process because of their complexity, creating competition for scarce equipment which has to be moved around and set up for use. The human factor in perioperative systems are the users themselves, both patients and healthcare providers. Current perioperative systems tax the cognitive capacities of both. To lessen the cognitive burden, systems are created which ultimately subject all stakeholders in the process to a tyranny of standard operating procedure.

The best perioperative systems highlight the potential for the application of basic principles of management and industrial design coupled with emerging technologies to smooth the flow of patients through future ORs. However, it has not yet been possible to assemble all of the available pieces in one project, and many pieces are missing altogether. Instead, today's pre-, intra and post-operative environments are characterized by: (1) an array of ergonomic deficiencies, (2) inefficient, ineffective and redundant processes, (3) fragmented communications and team integration, (4) inflexible 'systems' of operation, (5) staffing shortages (nurses and technicians) and (6) varying levels of competency among perioperative personnel. These factors contribute to an environment in which safety issues, frustration and inefficiency must constantly be combatted.

Current deficiencies are brought into sharpest focus when considering the intraoperative portion of perioperative systems design. In today's operating rooms, teams are fragmented, while communications are by voice, land-line telephone and grease board. When a team member leaves line-of-sight they effectively leave the team. Significant energy is diverted from patient care simply to make the ORs and their equipment function. Supply and equipment deficiencies cause wasted time. Information systems are used to a limited degree. The personalities and work habits of individual surgeons are a strong factor in the OR's function. The complexity of work is unrelentingly high. The workload is highly variable, and has intense peaks. Unplanned events occur frequently and in clusters causing unpredictable responses and high stress levels. This stress affects patient care and contributes to high employee turnover rate and burnout.

Example of Current State

The most technologically advanced operating rooms used today allow us to glimpse the potential of the fully realized OR of the future, while highlighting some of the problems described above. A specific example may be illustrative here. Recently, the Center for Integration of Medicine and Innovative Technology (CIMIT) developed a working OR of the Future in concert with TATRC and several industrial partners at the Massachusetts General Hospital. The objective of the CIMIT ORF project was to bring the most advanced intra- and perioperative technology approved for use with patients together in a single OR, with a commitment to keep the installation at the forefront of available devices. Included in the project were major physical plant changes to allow drastic modifications in workflow aimed at improving OR throughput. Extensive personnel resources were made available, and the CIMIT ORF quickly exceeded expectations with respect to patient throughput. The average time between the departure of one patient from the OR and the subsequent patient being ready for surgery was almost immediately cut by 60% relative to comparable conventional ORs doing similar cases (a mix of major intra-abdominal and routine laparoscopic procedures).

Three important qualitative observations arise from the early experience in the CIMIT ORF: first, improvements in one aspect of a Perioperative System Design highlight fragilities elsewhere in the perioperative system; second, the current state of technology is woefully unready for integration; and third, communication with team members 'over the horizon' is still virtually impossible.

The dramatic enhancement in OR throughput has had the effect of adding a catalyst to the rate limiting step in a multi-step reaction: a new rate limiting step appears elsewhere. For example, some preanesthetic evaluations from the MGH preoperative clinic are still recorded on paper, and hence are not available electronically. Moreover, the organization and policies of the preoperative clinic allows healthy patients to bypass a personal interview with the anesthesiologist. In such cases, responsibility for discussing anesthesia plans & procedures and obtaining consent falls to the ORF team. This adds to the intra-op team's workload and increases the likelihood of a day-of-surgery cancellation because of unaddressed anesthetic concerns. Similarly, the inability to consistently ensure that pre-surgical documentation (consent, history, etc.), are in the patient's record prior to arrival in the suite interrupts the surgeon's work. Limitations of the post-op phase of the Perioperative System have also appeared. For example, high occupancy in the hospital has caused all of the PACU beds to fill early in the day, which, in turn strands a patient in the early recovery bay, bringing the operation of the entire suite to a halt.

Integration of technology has been one of the major goals and persistent challenges in the CIMIT ORF. On the surgical side, integration of advanced surgical devices has depended upon cooperation between traditional competitors in industry. Enough progress has been made to appreciate the tremendous as-yet unrealized advantages full integration between devices would yield. Other systems are farther away from integration. For example, the anesthesiologist interacts with as many as four separate displays, each attached to its own computer: one for the hospital's patient information / order entry system, one for physiologic monitors, one for automated anesthesia record keeping and one for drug / supply management.

Communication in the CIMIT ORF is still most effectively carried out face-to-face. This leads to extensive round-tripping by team members throughout the suite for planning and information gathering. Analog walkie-talkies and cellular phones have been rejected as being insufficiently secure for patient confidentiality and too awkward to use. When team members leave the suite, communication degenerates to beeper pages and messages on the main OR PA system. Requests for supplies, technical support and custodial service between cases, as well as communication with OR administrators and other physicians are all by land-line telephone.

We suspect that similar sorts of system vulnerabilities have come to light during the development of other technologically advanced OR initiatives, and we cite the specific example above to point out the potential difficulties of integrating changes in a particular facet of perioperative design within a larger system. Hence, perioperative systems must be considered globally when making changes to one facet. In particular, upstream and downstream issues must be addressed in an effective Perioperative Systems Design.

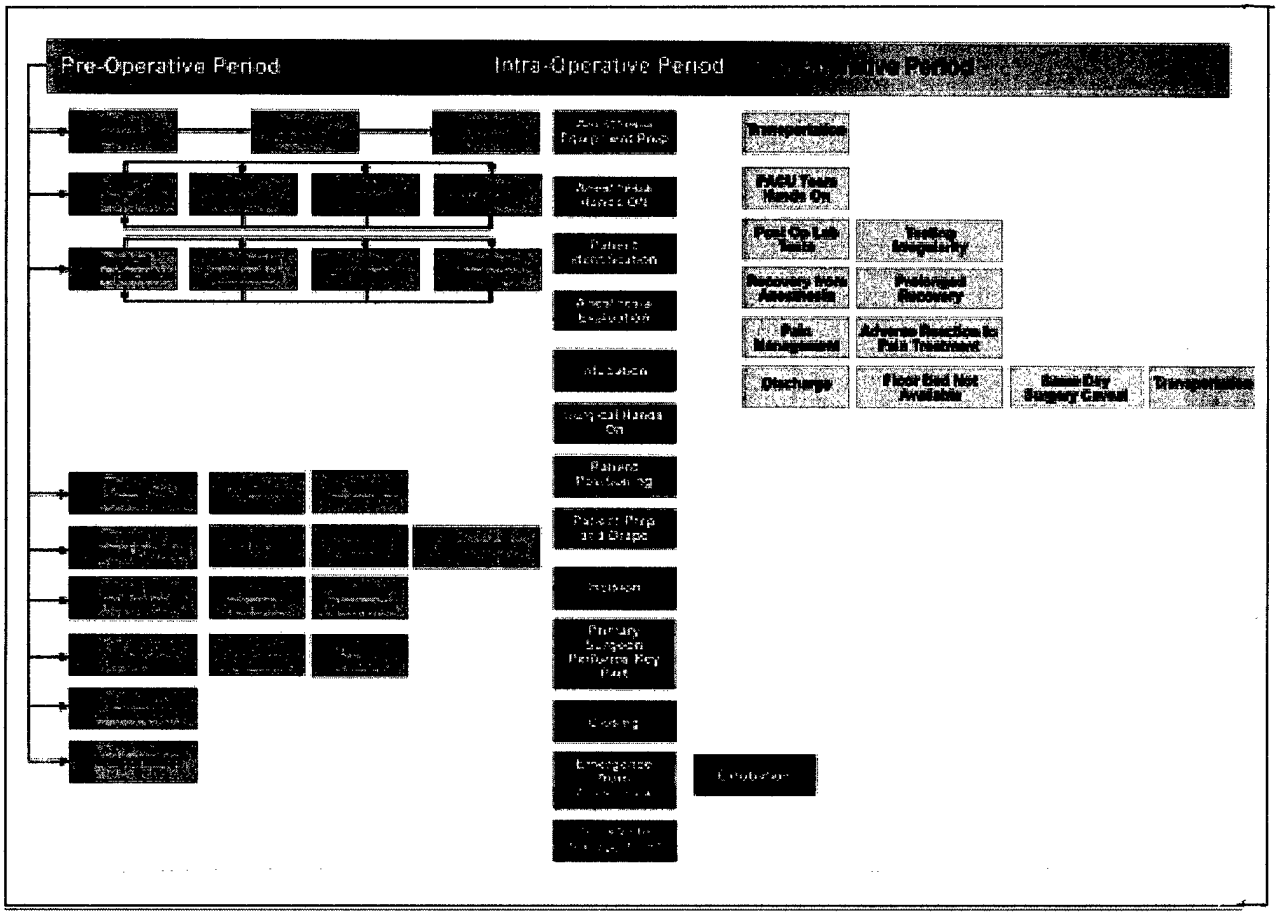
Perioperative Timelines

The CIMIT ORF experience illustrates that the perioperative process is actually a series of interconnected events. In practice, many steps in the perioperative process are completely dependent on the successful completion of the preceding steps. This sequential structure makes it useful to conceive of the perioperative process as a set of two nested timelines. The overall perioperative timeline begins with the decision to perform a procedure and ends with the patient's departure from the post-procedure recovery area. Nested within this overall timeline is the intra-operative period, which begins when the patient arrives in the OR area.

We have displayed a representative set of perioperative timelines in the following table. Milestone events are indicated in rough chronological order with no attempt to represent the

actual elapsed time between events. Events contained in parentheses are typical steps at which the perioperative process can derailed. It is readily apparent that the perioperative process is extremely vulnerable to perturbations, particularly during the critical intraoperative portion, when delays in a single case propagate downstream and ripple across the OR suite as well.

Table 1: A Representative Perioperative Timeline



Looking at the overall timeline shows that perioperative processes (and Perioperative Systems Design) extend far beyond the OR, both in space and time. In fact, perioperative processes, and their vulnerabilities are so distributed that they will truly require a multidisciplinary and holistic approach to designing improvements. Any planned change in Perioperative Systems must be considered in the context of the entire system, and the timelines are a useful construct for this purpose. Furthermore, any proposed research and development effort in Perioperative Systems Design should be evaluated in terms of its likely and potential favorable impact on the perioperative timelines.

Desired State for the Perioperative Systems

Today's operating rooms deploy an impressive array of stand-alone technologies. Current trends point to ever greater technological capability in diagnostic and therapeutic tools. We anticipate continued miniaturization of tools and equipment, more mature voice recognition and other communication technologies, and continued advances in robotics and imaging, leading to more and more non-invasive procedures. We have moved from the network decade of the 90s to the age of sensors today and will move another leap in the coming decade to the biotechnology decade as well as seeing the development and manufacture of nanoscale materials on a routine basis. These developments will allow the realization of the Perioperative System Design of the future.

Pre-operative Period:

From a patient's perspective, the ideal Perioperative System allows them to move from home to procedure and back to home seamlessly, comfortably and safely. From a surgeon's perspective, such a design allows them to transition smoothly between procedures and other clinical activities with minimal frustration while ensuring the safety and comfort of their patients. For the remaining stakeholders in Perioperative Systems, the ideal design provides a rewarding work experience by minimizing frustration and wasted effort, absorbing the effects of peaks in workload and unexpected events, while ensuring the comfort and safety of patients and healthcare providers alike.

Under the Perioperative System Design of the future, the patient will be the center of the process. Starting from the decision for surgery in the surgeon's office, expert software will assist with medical decision making. Referring to comprehensive databases of the patient's medical history, as well as aggregate and surgeon-specific outcomes experience for the contemplated procedure in case matched controls, decision support software will be able to suggest optimal pre-surgical testing, diagnostic studies and interventions to minimize perioperative risk. Interfaced with the patient's calendar and testing facility schedules, these programs will suggest and schedule dates for indicated tests.

Scheduling a case will create a secure website for the procedure to coordinate appointments, disseminate results to appropriate stakeholders and keep the patient apprised of their progress along the perioperative timeline. The patient will be able to review educational material tailored for their specific procedure within the context of their intercurrent medical conditions. Specific reminders, perioperative instructions and information (e.g., directions and drive time to the hospital under current traffic conditions) will be sent to the patient guided again by expert software.

Practitioner specific case lists linked to the individual patient / procedure sites will be available to anesthesia, surgical and allied personnel sufficiently in advance of the contemplated procedure to allow final interventions to be easily made prior to the day of surgery.

Prior to the day's cases, automated supply management will dispense supplies for each case based on a moving window of the surgeon's historical item utilization for the booked procedure. A second rank of less commonly used supplies and the items needed for the surgeon's most common 'changes' to the booked procedure will be identified by looking further back for infrequently used items. These will be readied in the background for rapid provision.

Passive sensor technology such as radiofrequency ID (RFID) tags in conjunction with sensors in key portals (e.g., doorways) will be used to track the progress of critical supplies,

devices and actors, monitored by expert workflow process software. When an incipient bottleneck is developing appropriate personnel will be alerted in time to avert the problem before its effects are felt in the OR. This technology coupled with time & motion data from more fine-grained sensors throughout out the OR will be used to detect the key events in each OR and infer the progress and projected end times in each room. This data will be used to balance the workload across the ORs by moving cases when appropriate. Again, this system will rely on expert workflow process software to to monitor the workflow and suggest interventions.

On the day of surgery, patients will participate actively in their own check-in process using their web-site to confirm the site and nature of surgery. The patient will don a beacon device that identifies them, tracks their location within the hospital and links authorized practitioners to their medical record and hospital information management / order entry system. Perioperative patients will also don a set of physiologic monitors that communicate through the beacon to the hospital information system. Physiologic monitoring will be continuous.

The anesthesia & surgical teams and appropriate OR personnel will be authorized to access the patient's electronic medical record and enter orders by RFID when in proximity to the patient and by more conventional means when working remotely. The interface will be a wireless hand-held device carried by the practitioner. The perioperative nursing record and the anesthesia record will be seamlessly integrated with the patient's hospital medical record. Location and process specific records (like the periop nursing record which is used to track personnel and equipment and the anesthesia record which is an information dense accounting of a period of intense interventions) will be created and maintained automatically when advanced sensors detect key events. Hence, the user interface for these documents will be completely transparent to the practitioner.

Intra-operative Period

Real time access to comprehensive medical knowledge databases will play a key role in guiding intraoperative management. For example, a system proposed by Gage (Gage 2002) will be operant: At the beginning of anesthesia, access to worldwide aggregate anesthesia record databases and practitioner-specific databases will be made by the anesthesia workstation. As the anesthetic progresses, comparisons will be made between the case at hand and matched historical controls. These comparisons will be used by decision support software to suggest optimal management. Moving beyond database connectivity, the anesthesia workstation will run physiologic models tailored to the patient's procedure and comorbidities. Divergence between model and patient behavior will intelligently activate alarms. Appropriate differential diagnoses of patient and equipment problems will be generated and displayed, along with context specific decision support information.

Operating room equipment, including surgical, anesthesia and ancillary patient support devices (OR beds, warmers, etc) will be fully integrated within and across categories. Equipment will be fully compatible at the software level, such that single controllers with user interfaces tailored for use by surgeons, anesthesiologists and nurses can operate all of the relevant equipment. Conversely, this equipment will be fully modular at the hardware level. This allows OR to optimally configured to the case at hand, but capabilities can be rapidly enhanced to cope with unexpected complications, and individual devices can be hot-swapped in the event of failure. All of the equipment in the OR will identify itself and report on its condition to the perioperative record, thus creating another database that con be used for utilization and quality assurance purposes.

The ideal user interface will display critical information saliently, while allowing easy access to comprehensive data. Recording and equipment control functions will reside in the same device. Requirements for manual data entry will be minimized by (1) automatic recording from therapeutic devices (ventilator, infusion pump settings) (2) using advanced sensors to detect and record key events (intubation, incision), or (3) voice recognition technology to record spoken announcements (drug, route, dose for example). The user interfaces for surgical, anesthesia and nursing workstations will reside on devices that are fully mobile, i.e., hand carried and wirelessly connected.

Voice communications in the OR will be hands free, wireless and secure, using voice commands to configure the circle of participants to the needs of the moment. This technology will allow easy and instant communication with other personnel throughout the OR. When a team member leaves the OR, they will remain in the communication loop. Enhanced video capacity will facilitate 'tele-surgery' consultations.

Intra-operative supply chain management will be as intuitive to use as today's supply cabinets and chest-of-drawer workstations, but with deeper reserves, broader inventory and software enhancements. In other words, for the user, obtaining an item should be as simple as removing it from its storage location. In the background, the system validates the user's authorization to access the supply, establishes the identity of the patient, associates patient with supply (allergy check / alert), documents use, registers charge, and links to central supply to ensure replenishment as well ass identify and ready likely follow-on items.

Post-operative Period

Recovery personnel will have access to all information relevant to their patient's intra-op course and preoperative issues prior to the patient's arrival in the post-anesthesia care unit (PACU). All patients will travel from the operating room to the PACU fully monitored, and the PACU record will simply be an extension of the anesthetic record.

Flexible spaces will be rapidly reconfigured to meet the recovery space needs. What sets the PACU of today's OR apart from any other unit in the hospital includes a cadre of highly skilled nursing and physician personnel, piped oxygen and vacuum, physiologic monitors and a specific set of supplies. The availability of monitors is frequently the largest infrastructure impediment to adding PACU capacity due to their high cost. In the PACU of the future, patients will arrive wearing their monitors. Equipment miniaturization will have arrived at the point that all that is needed to support a mobile "PACU workstation" including oxygen, vacuum, a display for monitors and a set of supplies will be a source of electricity and access to a wireless LAN. Using such mobility of infrastructure it will be possible to reshape flexible spaces into traditional PACU bays, ambulatory recovery space, overnight critical care beds or ambulatory PACU spaces, based on the projected needs from the day's workload.

Smart scheduling software will predict periods of peak demand for PACU services and schedule personnel appropriately.

Summary

The OR of the Future will be characterized by intuitive communications and sensor technologies that reduce or eliminate medical errors, provide complete 24 hour situational awareness to clinicians, support staff, and management, and support the creation and nurturing of highly trained and cohesive teams. These environments will be scalable.

In the future surgical environment the patient will be the primary focus. The healthcare facility of the future will use technology to improve both the efficiency and effectiveness of

the delivery process. This includes the flow of people, information and materials, the integration of human systems into these technologies.

Recommended Research Roadmap

The Perioperative Systems Design workgroup was in agreement that safe and efficient Perioperative Systems are critical to both military and civilian contexts. However, today's complex perioperative processes, sometimes perceived as chaotic, unwieldy, and frustrating, have grown up without direction in response to developments in surgical practice and technology. Consequently, the benefits of new surgical techniques and high technology have been dampened by inefficient perioperative systems. Now, there is a need for research and development in several areas that defy easy sorting into specific projects. Accordingly, we present two schemas for organizing this research effort. The first is based loosely on categories of effort within Perioperative Systems Design, and might at first glance lend itself to the evaluation of technological innovation in Perioperative Systems. The second research schema is meant to invite researchers to consider their work in terms of the overall goals of Perioperative Systems Design. This second, goal oriented schema is meant to provide an encompassing framework for the critical evaluation of research within the global context of an entire Perioperative System.

Category Research Roadmap

The Perioperative Systems Design workgroup identified eight major category areas for research which were labelled: Safety, Integration, Connectivity, Information, Equipment, Outcomes, Facility Design and Personnel. Some of these categories also drew the attention of the other four workgroups, in some cases forming the bulk of their efforts. They are re-treated here for the sake of completeness and to stress the idea the Perioperative Systems Design encompasses the complete care of the patient from admission to discharge. The research categories identified by the other workgroups that are most relevant to the multi-disciplinary focus of our workgroup are highlighted below in the first six items:

Safety The Patient Safety workgroup viewed safe care as a pre-condition and first priority in surgical settings (Beyea et al. 2002), and we took this to include all patient settings considered in Perioperative Systems Design. The Patient Safety workgroup pointed out that ensuring safety was consistent with patient-centered care and achieving optimal outcomes. The group also recognized that the majority of errors result from poorly designed systems and clinical processes, and are not the fault of individual clinicians (Beyea & Kilbridge 2002). The Telemedicine workgroup advocated the use of teleconsultation to broaden the resources brought to bear on intraoperative processes, as well as the use of high resolution recording of complete intraoperative data for later analysis of critical events (Merrell et al. 2002).

Integration The OR Informatics and Advanced Devices workgroups both focused on equipment datastream and information integration as areas for development (Minear et al. 2002; Rattner et al. 2002). Both workgroups commented on the impressive capabilities of stand alone equipment and lamented their lack of integration with each other. The Advanced Devices workgroup focused on the increasing number and types of sensors that clinicians monitor and control (Rattner & Park 2002). Pointing out the limitations of human ability to capture, process and integrate raw datastreams, a call was made for research into data capture and use, optimized for both real-time analysis and after the fact interpretation (Rattner & Park 2002). The Informatics workgroup called attention to the fragmentation of medical information from clinical resources such as labs, medical records and databases (Minear & Sutherland 2002).

Connectivity The Advanced Devices workgroup stressed the importance of device interconnectivity:

> Current devices neither communicate with each other nor with common interfaces. All devices in the future should be able to be seamlessly plugged into a network for control, data capture, and safety. A DICOM like standard needs to be created for all equipment used in future ORs. Furthermore, this standard needs to provide interoperability in both civilian and military environments (Rattner & Park 2002).

Although the Advanced Devices workgroup focused primarily on surgical equipment, their position on connectivity logically applies to all devices used in Perioperative Systems, especially since some devices, such as procedure surfaces, fall within the control of multiple OR stakeholders. Connectivity was also a focus of the Medical Informatics and Telemedicine workgroups, again, primarily for intraoperative devices (Merrell et al. 2002; Minear & Sutherland 2002).

Information The Telemedicine workgroup commented on the tremendous amount of information that passes without being captured or recorded in the typical operating room, and called for the development of technology to capture, broadcast and record surgical procedures (Merrell et al. 2002). The Advanced Devices workgroup called for developing technologies and methods to extract relevant information from voluminous data both for intra-operative guidance and post-operative analysis (Rattner & Park 2002). The Informatics workgroup emphasized the need for 'smart' software to assist with decision making for complex datasets and the development of standards for information management to make complete medical information fully accessible (Minear & Sutherland 2002).

Equipment Both the Advanced Devices and Informatics workgroups touched on the need to improve the OR worker's user interface. The Advanced Devices workgroup couched this discussion in terms of managing datastreams and integrated device control for surgeons (Rattner & Park 2002). The Informatics workgroup extended this notion, calling for research to:

> Design and test the optimal User Interface (UI) for surgeons, anesthesiologists, and nurses to input and access clinical data. The optimal UI will support multi-mode access, where clinicians are able to use Mobil devices (such as the PDA or tablet computers), Internet browser access to Intranets, and adequate remote access through secured Internet connections (Minear & Sutherland 2002).

The Perioperative Systems Design workgroup embraces the need to rethink and reconfigure the user interfaces for all OR workers, with an emphasis on integrated data capture, real time analysis, access to patient records and medical knowledge, coupled with device control.

Outcomes A recurring theme from the other workgroups was the need to demonstrate return on investment from potentially expensive OR of the Future research initiatives. For example, from the Advanced Devices workgroup comes this mandate:

> In order to fully capture the purported benefits of the components of the OR of the Future as well as the efficiencies of systems integration, it is necessary to model, predict, and then measure the effect of different patient flow schemes, different staffing models and room functionality in the presence or absence of its various components. Only by performing such a detailed analysis can one justify the potential added expenses of such a sophisticated

OR environment and identify areas of waste which should be modified or eliminated from the design (Rattner & Park 2002).

The Patient Safety workgroup chose to focus on outcomes measurement from a quality assurance perspective. They advocated using the sophisticated data collection capability of a realized OR of the Future to identify the true incidence and prevalence of adverse events, to determine the cost of adverse events and to demonstrate the cost-effectiveness of initiatives to ensure safety (Beyea & Kilbridge 2002).

Two additional general issues pertaining to the OR of the Future and identified by the Perioperative Systems Design workgroup are Facility Design and Personnel.

Facility Design The pace of technological innovation will only continue to accelerate. Thus it is likely that disruptive technological breakthroughs will occur more than once during the lifetime of the buildings erected to house the OR of the Future. Thus, hospital facilities of the future must be designed to support and nurture technological innovation. In conflict with this notion, today's hospitals grow by accretion and renovation, rather than creation from scratch. Research in Perioperative Systems Design should include consideration of how spaces can be made more accommodating to new technology, and how new technologies can be used to extend the capabilities of existing space.

Personnel The OR of the Future will accelerate the onslaught of new technologies and their associated cognitive load on the people who work there. Without proper attention to the care of individuals (caregivers and, to a lesser extent, patients) using the workspace, future ORs may exceed the capacities of their designers. This issue encompasses but goes beyond ensuring the safety and comfort of personnel. New technologies may require completely reconfiguring the OR workforce, redefining work roles and redistributing tasks. Ironically, in future ORs it may be surgeons whose capacity for work is exceeded, as improved perioperative systems quicken the tempo of patient flow through the perioperative timeline.

Goal Oriented Research Roadmap

Perioperative Systems Design cuts across all aspects of the care of the surgical patient. It intersects all of the issues addressed by the Safety, Informatics, Telemedicine and Advanced Devices Workgroups. Research critical to improving Perioperative Systems Design may not lend itself to organization under the category schema described above. For example, research into advanced devices to automatically select and deliver supplies to the OR in a timely fashion will touch on Safety, Equipment, Connectivity, Information, Integration and Facility Design in the category schema, but it might more easily be described as an effort to improve readiness in the OR. To address this we have developed a second research schema by defining four broad concepts pertaining to the fundamental goals of Perioperative Systems Design research. These goals encompass the 'why' of Perioperative Systems Design research, and any proposed effort must be critically evaluated with respect to how it impacts them:

Readiness Pertains to the ability of the perioperative process to be fault-tolerant as well as self correcting, and to gracefully accommodate unanticipated events.

Workflow Addresses the optimal design and deployment of resources and processes associated with the pre-, intra- and post-perioperative timeline.

User Expectations Addresses the needs of the users of the surgical environment, including patients, the surgical team and other aligned clinicians. Expectations may range from the emotional, e.g. reducing frustration, increasing satisfaction, to the physical, e.g. reducing fatigue and stress. In addition, expectations may emanate from awareness of technological

progress in other industrial and cultural settings e.g. use of wireless bar-coding in retail, robotics and machine assisted tasking in manufacturing, customer service models enhanced through connectivity with the internet, etc.

Training Addresses enhanced competency of the perioperative team – individual and collectively – before during and after the surgical process and the development of a learning environment in surgery.

The Perioperative Systems Workgroup advocates that any research pertaining to the OR of the Future be considered in light their impact on the perioperative timelines and in terms of these four concepts. For example, a new technology based in one of the eight categories may be developed to address specific *user expectations*. However, if this technology requires skilled operators, unique supplies or any other scarce resource is likely to have a negative impact on overall *readiness*. This may be mitigated if sufficient attention is paid to *workflow* issues during development and deployment of new technology. New technologies should always be developed with an eye to training, if only to maximize their ease of introduction and realize their full potential.

Summary

The issues involved in designing and deploying optimal Perioperative Systems are multi-disciplinary, and will draw input from the following fields:

- Industrial engineering and systems engineering for production system designs, workflow design, systems analysis, and quality assurance.
- Human factors/ergonomics for workplace layout, safety, and training
- Computer science / human-computer interaction for user-centered information systems, and easy to use computer systems
- Management science for staffing, retention, and organizational behavioral analysis.

Given the breadth of the topic, it is easy for research to occur in apparent isolation, based primarily in one of the disciplines listed above. Hence, a central goal of the Perioperative Systems Design Workgroup is to create a basis for a cohesive and mutually supportive academic and industrial engineering community focused on the surgical environment. To facilitate this goal, the Workgroup created two schemas for research and solution development, one based on broad categories, the other based on goals of the perioperative process. We believe that these schemas will facilitate research programming and funding to target operational goals relevant to most stakeholders in the surgical environment.

Recommended Research Agenda

In the previous section, we have laid out eight major topic areas for research in the OR of the Future, and established a framework for considering which goals of Perioperative Systems Design that specific research projects might address. To accomplish the creation of the desired state of technology in future Perioperative Systems, a concerted research effort in several more specific areas must be undertaken. These are laid out below. In some cases the divisions between topics seem almost artificial because topics are so closely related and draw so heavily upon each other.

A major *workflow* goal throughout the research effort must be directed at reducing the number of user interfaces that healthcare personnel must address, and equally importantly, making these interfaces more transparent. Here, we define "transparent" as a combination

of intuitive to use and requiring minimal interruption in the user's primary activity, patient care.

Facilities: The rate of change in medical technology will only increase. Robust demonstration of a new technology's effectiveness through outcomes projects will increase the urgency of its widespread deployment. This will lead to increased pressure on hospital facilities to provide a reconfigurable infrastructure. Future hospital design should focus on providing spaces designed for maximum flexibility and anticipating the need to reconfigure the space. For example, interior partition walls should be engineered so that they can be added to a large, finished space like furniture, with impervious surfaces pre-applied, and devoid of wiring or plumbing. Reconfigurable partitions can be achieved by inclusion of services in ceilings and accessed by pendants (electricity and gases), while wireless connectivity and portable, battery powered user interface devices will obviate the need for LAN connections or telephone connections in many walls. This research effort can be expected to pay large dividends in terms of workflow and user expectations for the life of a successful building. Developing and testing the basic concepts for a flexible hospital space should be a short term undertaking.

Communications: Communications can be (somewhat artificially) divided into person-to-person voice and person-to-group non-verbal blocks. Both will retain their utility in the Perioperative System Design of the future, and both require significant research and engineering effort to realize their full potential.

Voice communication will continue to be a mainstay for conveying instructions and data, and for synchronizing the information state and plans among team members. What will be different about the OR of the Future is that people will communicate with equipment and the medical record in much the same way as they communicate with each other: by voice. All of this functionality must be delivered without restricting the mobility of personnel. Hence the need for continued development of ergonomically perfect, wearable, hands-free, wireless voice communications devices.

There are other forms of communication currently in use that must gain new functionality to fulfill their missions in the ORF. For example, the ubiquitous 'dry-erase' white board is likely to persist, if only because it is so effective for broadcast communication and providing visual organizing cues. Research in areas of non-voice communication must focus on capturing the data put on such 'big-picture' devices by people so that it can be used by decision analysis programs. Basically, people must be able to communicate with software and databases via the white board. Similarly, the software and databases must be able to use the same device to communicate with people without destroying its functionality. In a related area, paper documents have a representational value of the big picture. Current software designed for electronic recording of data traditionally represented graphically on paper must be engineered so that this graphic information is returned to the display of data.

As the cost of sophisticated equipment falls and technology continues to develop, we anticipate that significant steps toward the desired state in communications can be achieved in 3-5 years, with major benefits to the intraoperative timeline in terms of workflow, readiness, user expectations and training.

Patient Monitors Today's 'conventional' physiologic monitors require miniaturization and application of short-range wireless technology to make them full-time wearable and free of leads. "Put them on once, always on" wireless monitors for patients should be a short term research focus. Once in the perioperative environment, vital signs should always be monitored, and they should be monitored without tangled, contaminated leads that must be removed/reapplied with each change of location. Creating this monitor architecture allows

the patient to be monitored wherever there is a display, since the monitoring hardware and software will be on the patient, rather than the wall. We expect that this level of technology could be achieved in 3-5 years, with modest improvements in perioperative workflow but a dramatic impact on perioperative readiness (the ability to anticipate and react to physiologic perturbations foreshadowing catastrophic events).

Effective monitors of each of the major anesthetic interventions: hypnosis, analgesia and paralysis would be beneficial and merit further research. Two of these three monitors are available in some form, while the third (analgesia) remains a long term goal. Having all three integrated and consistently deployed could yield significant improvements in perioperative workflow.

Advanced sensors to detect and quantitate drug administration would be beneficial, in that it would remove the need for human involvement in documentation. Such technology is probably a longer term goal (i.e., ten years).

Perioperative Medical Informatics: The ideal Perioperative System in the OR of the Future depends entirely on having complete information about patient, disease, surgeon, procedure, anesthesiologist, etc., all available in the same place for use by people and expert software. Much of the required information is already gathered and stored in today's perioperative systems, but not always electronically and never in a single database. Hence, we endorse the research agenda set forth in the White Paper on Medical Informatics. Related areas of research necessary to use the accumulated data prospectively and effectively are laid out below:

> *Standards for Database Connectivity:* Proprietary standards for databases have grown up for a variety of reasons. While it may suit the purposes of the developers and owners of today's medical databases to limit their connectivity, the OR of the future will not be realized if such silos of information are allowed to continue. Establishing the framework for a single access point for all patient information, as well as the required data about practitioners will require a basic science effort by academic researchers coordinating with the research work done by industrial developers. The necessary standards are not likely to grow out of a competitive marketplace, so a regulatory contribution to this effort is likely to be required. Finally, legislative work to protect the privacy of patients and practitioners in an era where *complete* data about both are known and readily accessible will be necessary. This aspect of the research effort should be accomplished in the short term. Although standards for connectivity will have little direct impact on perioperative timelines, they are a required step for enabling much more dramatic improvements through ready access to information.
>
> *Expert Software:* We anticipate that several areas in the Perioperative Systems Design of the future will require decision assistance provided by expert software. Such software has been described as having 'knowledge inside' (Minear & Sutherland 2002), and will be used in three overlapping sets of circumstances: (1) to optimize decision making when the number of variables affecting the decision exceeds human cognitive capacity (e.g., scheduling), (2) to bring aggregate medical knowledge (historical and prospective research) and patient-specific data into the decision making process, and (3) to make lower level decisions autonomously in the background (picking supplies for routine cases). Scheduling software, both for day of surgery and for the entire perioperative period will remove much of the apparent chaos found in today's ORs, and will smooth out the effects of

unanticipated events by quickly adjusting schedules to accommodate new circumstances. To do this, such software will need access to complete data about all actors. Wide application of expert software depends on standards for information sharing and seamless access to complete data. Once achieved, huge improvements in perioperative readiness and workflow are likely. However, this is likely to remain an intermediate term goal (5-7 years) while the prerequisite steps are accomplished.

Voice Recognition: Voice recognition for the purpose of controlling devices and software has the obvious advantages allowing the users hands to be doing something else, and preventing contamination of the user interface. Voice recognition for control of devices, query of databases and use of software will be a near-universal feature of Perioperative Systems Design in the desired state of technology. Research in the areas of informatics, information standards and expert software should all proceed with the assumption that the mode of instruction input will be voice. Initially the direct impact of voice recognition devices on perioperative timelines may be modest improvements or even counterproductive. However, as voice recognition establishes itself as a part of intuitive, easy to use interfaces, its impact on workflow will become more positive.

Single User Interfaces Optimized for Target Users To create an environment where clinicians focus on the care of the patient rather than the control of devices, interaction with medical equipment must become intuitive and transparent. Redundant actions must be eliminated and all relevant information and control elements placed within easy reach of the user. The intraoperative user interfaces might ideally reside on a tablet computer based device. Key features will be wireless connectivity and mobility within the OR, and the ability to tolerate high level disinfection between cases. Perioperative personnel will also need a smaller, PDA-like device for interacting with patient medical records, the hospital order entry system and imaging displays for use in the pre- and post-operative period. Such a device should be hand held and fit in a pocket. The development and testing of optimal user interfaces for each member of the perioperative team should be a primary goal in Perioperative Systems Design. This research goal touches on the informatics, standards, expert software, voice recognition and communications research topics above, and echoes a primary research goal of the Informatics Workgroup (Minear & Sutherland 2002). Because the optimal user interface depends on achieving all of the information connectivity described above, and the plug and play device architecture (below), it is probably farthest from realization. However, research in this area will contribute significantly to meeting user expectations and improving workflow.

Plug & Play, Modular OR Equipment Creation of single user interfaces implies taking over control of devices and receiving data from sensors remotely and independently from whatever user interface was supplied with the device. Realization of an optimal, unitary information and control interface requires creation of technology to allow software level seamless integration of all OR equipment in such a way that all of its functionality can be invoked by another device. Technology will continue to be acquired and deployed piecemeal to avoid the cost of replacing usable equipment that is not obsolete. Hence hardware modularity and interconnectivity should become engineering and design objectives. The drive towards modularity will also be supported by the need for flexibility in how equipment is deployed from case to case. What we are describing is the creation of a plug and play environment for OR equipment similar to the one that is just coming to fruition for personal computing. This will require collaboration, or at least cooperation between traditional competitors, and might best be sponsored by creating a government / user / industry consortium to develop the necessary standards to support the needed interconnectivity.

Development of plug and play OR equipment reiterates a major research goal of the Advanced Devices Workgroup (Rattner & Park 2002) and extends it to encompass all of the equipment used in Perioperative Systems. Developing plug and play perioperative technology is a prerequisite to constructing optimal perioperative user interfaces, and should be made an urgent short term priority with an expected 3-5 year deployment timeframe for all OR equipment. Moreover, plug and play modular equipment will yield significant improvements in readiness, workflow and user expectations in its own right as it becomes available.

Perioperative Advanced Devices Advanced devices for supply chain management and process monitoring await research and engineering development.

Perioperative supply chain management is waiting for the application of robotics and expert software to completely automate the picking and delivery of supplies for surgery, anesthesia and ancillary patient care, both preoperatively and intraoperatively. Research and engineering in this area should focus on creating secure supply delivery with a completely passive, transparent user interface. Robotic picking, delivery and dispensing of drugs and supplies, assisted by expert software for decision assistance and autonomous decision making should be a research focus. Machine learning algorithms could be applied here in conjunction with historical data mining to predict what supplies will be needed and deliver them to the therapeutic location preemptively. As with all of the other perioperative technology implemented in the Perioperative Systems Design of the future, these elements should be developed as software-integrated hardware-modular plug and play devices. These technologies will have major positive impacts on readiness and workflow. In many cases the technological hurdles have been cleared in other fields such as manufacturing, and what is needed is an effective transfer to Perioperative Systems. This could be accomplished in a 3-5 year time frame.

Part of the optimal user interface for any procedure based practitioner is the interface device's ability to infer where in the process the system is at the current time and to offer an intuitive, context based, focused set of next moves on the control side, while automatically recording complete data and displaying that which is most relevant. The user should have minimal intrusions on their attention to the patient from both the control and recording sides of the user interface. To achieve this capability to infer system states and procedure progress, the perioperative user interface devices that are developed will require inputs from advanced sensors. For example, such devices might include advanced optical sensors and image analysis software to infer, in conjunction with data from the gas analyzer, when intubation has occurred during induction of anesthesia, or when the penultimate suture of a given type has been removed from the scrub table, prompting the delivery of another. These technologies will have major impacts on readiness, workflow, user expectations and training. However, they will require huge amounts of processing power and connectivity, as well as development of the sensors themselves. Thus, they are more likely to be deployed on the 7-10 year timescale.

Conclusion

We begin by restating an essential definition:

> *Perioperative Systems Design describes a rational approach to managing the convergent flow of patients having procedures from disparate physical and temporal starting points, through the operating room and then to such a place*

and time where future events pertaining to the patient have no further impact on OR operations.

In contrast to the notion of perioperative systems design, today's complex perioperative processes have grown up without direction in response to developments in surgical practice and technology. Consequently, the benefits of new surgical techniques and high technology have been dampened by inefficient perioperative systems. Perioperative processes are so distributed, and their vulnerabilities are so pervasive that they will truly require multidisciplinary and holistic approaches to their reconstruction.

We have presented two schemas for organizing the research effort in Perioperative Systems Design. The first is based loosely on categories of effort: Safety, Integration, Connectivity, Information, Equipment, Outcomes, Facility Design and Personnel. The second research schema is meant to invite researchers to consider their work in terms of the overall goals of Perioperative Systems Design: Readiness, Workflow, User Expectations and Training. Our goal oriented schema encourages critical evaluation of research within the global context of an entire Perioperative System.

Referring back to the perioperative timelines, it is clear that perioperative processes are extremely vulnerable to perturbations, particularly during the critical intraoperative portion. Making the Perioperative System more robust and fault tolerant is a key goal. Any proposed research and development effort in Perioperative Systems Design should be evaluated in terms of its impact on the perioperative timelines, i.e., what is its likely contribution to improvements in readiness and workflow, meeting user expectations and enhancing training in the OR of the Future.

Suggested Collaborators for Perioperative Systems Design Research

Application of new technologies to Perioperative Systems Designs for the OR of the future must be driven by the organizations that will use them in order to accommodate the unique features of the deployed locations. However, this will ideally be a collaborative effort led by the users, rather than work done in isolation. Industry will play a key role in the development of perioperative technologies. Equipment manufacturers have the critical masses of engineering talent and production capacity to design, develop and build new technologies. Clearly there is a role for OR of the Future implementation projects to push technology and systems to the limits of their designs, pointing the way for future development. These projects should also serve as test beds for potential new technologies and systems. Umbrella organizations like TATRC will play key roles in facilitating (1) the interaction between users and developers, (2) identify areas of mutual interest between traditionally isolated parties and (3) bring various stakeholders together. Finally, standards organizations with broad representation from all parties will play a strong role in developing the needed software and hardware standards for interconnectivity.

Bibliography

Beyea, Suzanne C. and Kilbridge, Peter, Setting a Research Agenda on Patient Safety in Surgical Settings, TATRC, Report No. 02-01, September, 2002

Gage, John S., Anesthesia Information Management Systems. ASA Newsletter 2002; 66 (6).

Merrell, Ronald C., Jarrell, Bruce E., Schenkman, Noah S., Schoener, Bradley and McCullough, Kathy, Setting a Research Agenda on Telemedicine for the OR of the Future, TATRC, Report No. 02-03, October, 2002

Minear, Michael N. and Sutherland, Jeff, Medical Informatics, A Catalyst for Operating Room Transformation, TATRC, Report No. 02-02, October 2002

Rattner, David W. and Park, Adrian, OR of the Future, Advanced Devices, TATRC, Report No. 02-04, October 2002